NCST **UNEP** **GEF**

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KENYA

PROCEEDINGS OF THE WORKSHOP ON THE

HANDLING OF REQUESTS (APPLICATIONS) FOR NBC & IBC MEMBERS

25th– 28th AUGUST 2004

MERICA HOTEL NAKURU, KENYA

NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY
October 2004

Abbreviations

AIA - Advanced Informed Agreement
ARIPO - African Regional Intellectual Property Organization
ASARECA - Association for Strengthening Agricultural Research in East and Central Africa
BCH - Biosafety Clearing-House
Bio EARN - Eastern African Regional Programme and Research Network for biotechnology, biosafety, and biotechnology policy development
BTA - Biotechnology Trust Africa
CBD - Convention on Biological Diversity
CBI - Confidential Business Information
CEO - Chief Executive Officer
COP - Conference Of Parties
CPB - Cartagena Protocol on Biosafety
DBT - Department of Biotechnology
DNA - Deoxyribo-Nucleic Acid
DVS - Department of Veterinary Services
EA - Environmental Assessment
EIA - Environmental (Ecological) Impact Assessment
GM - Genetically Modified
GMO - Genetically Modified Organism
IBC - Institutional Biosafety Committee
IBSC - Institutional Biosafety Committee
KARI - Kenya Agricultural Research Institute
KEBS - Kenya Bureau of Standards
KEPHIS - Kenya Plant Health Inspectorate Service
LMO - Living Modified Organism
NBC - National Biosafety Committee
NBPGR - National Bureau of Plant Genetic Resources
NCST - National Council for Science and Technology
NCC - National Coordinating Committee
NEMA - National Environment Management Authority
NEPAD - New Partnerships for African Development
NFP - National Focal Point
NGO - Non-Governmental Organization
SOPs - Standard Operating Procedures
UoN - University of Nairobi

Executive summary

This document gives the proceedings of the workshop on handling requests for NBC and IBC members, held from 25 to 27 August 2004 at Merica Hotel Nakuru, Kenya. It provides a short overview of what has been achieved so far in the implementation of Kenya's biosafety strategy, which was one of the objectives of this workshop. Other objectives were to train the NBC, IBC and regulatory agencies on (i) how to handle requests (applications) as stated under the Cartagena protocol, (ii) on Kenyan obligations and rights under the Cartagena Protocol with special emphasis on risk assessment, (iii) on the implementation of Article 8,9,10 and 15 of Cartagena Protocol on the proposed Biosafety Act of Kenya, (iv) on the administrative tasks and institutional requirements under the Cartagena Protocol, and (v) on the the general principles and procedures for risk assessment including decision-making, in relation to Cartagena Protocol.

Short summaries of the presentations made by invited experts and various other speakers are included. Follow up issues, conclusions reached during the workshop and the way forward are also included. These include a number of actions that are required to ensure that the Kenyan strategy is in line with the Cartagena Protocol on Biosafety and a number of actions that are likely to be important for any future strategy.

The following is a summary of the actions and tools that were itemised by the workshop rapporteurs and consequently agreed upon by the participants of the workshop. The full list of issues agreed upon as requiring follow-up is given in chapter 11 (follow up issues).

Agreement was reached that the ideal strategy requires the application of the actions and tools as indicated in the Cartagena Protocol. Realistic timeframes should be set for the various processes required by the Cartagena Protocol. Progress needs to be reviewed constantly and, when required, the direction amended.

The evaluation process for applications for trials using transgenic plants, animals or organisms and public awareness were identified as major activities that required much time and attention. Public awareness campaigns would help enhance acceptability and cooperation in strategy development by the stakeholders. It became clear during the workshop that NBC and IBC members needed training to better understand the expectations of the Cartagena Protocol.

From analysis it became clear that the current operational procedures in evaluation of applications required review. It is important to ensure that the review envisaged in the proposed Biotechnology and Biosafety policy and Biosafety bill are in line with the Cartagena Protocol and that the proposed system for administration, management, monitoring and evaluation are performed by independent bodies with the necessary technical and socio-political insight.

It was also recommended that alternative and diversified sources of funding be identified so as to make NBC work sustainable after the exit of assistance form UNEP-GEF and other development partners.

The list of registered participants is attached in Annex 1. The Agenda of the Workshop is attached in Annex 2. The Agenda was adopted.

Table of contents

Abbreviations **2**
Executive summary **3**
Table of contents **4**
1.0 INTRODUCTION **6**
1.1 Opening Ceremony 6
1.1.1 Welcome Address by Professor G.K. King'oriah, National Council For Science And Technology. 6
1.1.2 Opening Statement by Hon. Dr. Kilemi Mwiria, Assistant Minister, Education, Science & Technology 7
1.1.3 Responses to the Opening Statements 8
1.2 Overview of this workshop 9
2.0 PRESENTATIONS **9**
2.1 Biosafety Requirements and Institutional framework 9
2.1.1 Country Obligations and Rights under the Cartagena Protocol on Biosafety by Charles Gbedemah 9
2.1.2 Implementation of Article 18 of Cartagena Protocol in Kenya by Ms Rachel Shibalira 15
2.1.3 Administrative Tasks and Institutional Requirements under the Cartagena Protocol by Dr. Fee Chon Chong-Low 16
2.1.4 General Principles & Procedures for Risk Assessment as per Cartagena Protocol by Dr. S. Shantaram. 18
2.1.5 Discussions 19
2.2 Global Applications of Biotechnology and Biosafety 20
2.2.1 Safe use of biotechnology for improving of human welfare in developing countries by Dr. Phelix Majiwa 20
2.2.2 Generating transgenic crops and basic molecular analysis of GMO Crops – Dr. S. Annadana. 20
2.2.3 Discussions 22
2.3 Review of applications 22
2.3.1 International Norms by Dr. S. Shantaram 22
2.3.2 Overview of previously approved applications and Kenyan procedures and guidelines 23
2.3.2.1 Bt. Cotton Application by Ms. Lucy Gitonga 23
2.3.2.2 Transgenic Cassava Application by Dr. S. Gichuki 25
2.3.2.3 Recombinant Rinderpest Vaccine Application by Dr. Rosemary Ngotho 26
2.3.2.4 Application to Introduce bt Maize in Green House in KARI by Dr. B. Odhiambo 28
2.3.2.5 Kenyan Regulations and Procedures for Contained Use by Dr. Miriam Kinyua 28
2.3.2.6 Kenya Procedures and Regulations for Confined Field Trials by Mrs. Grace Thitai 30
2.3.2.7 Notification/Application Procedures for Field Trials in Kenya by Dr. B. Odhiambo 32
2.3.2.8 Review of the Kenyan Application Procedures by Dr. Phelix Majiwa 33
2.3.2.9 Discussions on Review of Applications 35
2.3.3 Presentations focusing on Lessons Learnt 36
2.3.3.1 Lessons Learnt by Kenya from handling applications & Procedures Followed by Dr. B. Odhiambo .. 36
2.3.3.2 Lessons Learnt from handling applications in India by Dr. S. Seetharam Annadana 37
2.3.3.3 Discussions on Lessons Learnt 38
2.4 Presentations focusing on Risk Assessment 39
2.4.1 Assessment of potential risks to environment & human health posed by GM crops by Dr. Shantharam .. 39

2.4.2 Risk assessment of transgenic cassava & recombinant rinderpest vaccine – a "hands-on" exercise by Dr. Shantharam and Dr. Seetharam Annadana 40
2.4.3 Legal assessment and comparison of Biosafety regulations in relation to Cartagena protocol on Biosafety, WTO and Africa Model Law by Gregory Jaffe.....40
2.4.4 Monitoring and Inspection Manual by Dr. Joseph M. Macharia 42
3.0 WAY FORWARD/FOLLOW UP ISSUES 44
4.0 CLOSING CEREMONY.....46
4.1 Closing Statement by Prof. Titus Mukiama, Department Of Botany, University of Nairobi's 46
4.2 Closing Remarks by Minister for Agriculture, Hon. Kipruto Arap Kirwa, M.P – *Read on his behalf by Mr. John K. Meli, Rift Valley Provincial Director of Agriculture, Ministry of Agriculture.* 47
5.0 ANNEXES.....49
Annex 1: List of participants 49
Annex 2: Workshop Programme.....53
Annex 3: Welcome Address by Professor G.K. King'oriah, National Council for Science and Technology.....56
Annex 4: Opening Speech by Hon. Dr. Kilemi Mwiria, Assistant Minister for Education, Science & Technology..58
Annex 5: Closing Speech by Prof. Titus Mukiama of the University of Nairobi's Department of Botany.....61
Annex 6: Closing Speech by the Minister for Agriculture Hon. Kipruto Arap Kirwa, M.P.....63

1.0 INTRODUCTION

1.1 Opening Ceremony

The workshop was opened by Hon. Dr. Kilemi Mwiria, Assistant Minister for Education Science and Technology, after short introductory addresses by the UNEP-GEF Project Manager Dr. Fee Chon Chong-Low and the Executive Secretary of the National Council for Science and Technology(NCST) Prof. George K. King'oriah.

1.1.1 WELCOME ADDRESS BY PROFESSOR G.K. KING'ORIAH, EXECUTIVE SECRETARY, NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY.

In his welcome address (see Annex 3 for full text), Prof. King'oriah expressed gratitude to the Hon. Assistant Minister for Education, Science and Technology for finding time to officially open this workshop on handling requests (applications) for NBC and IBC members.

He said that Kenya has undertaken biotechnology activities in the fields of agriculture, health, environment and trade and emphasised that the National Council for Science and Technology (NCST) continues to be at the forefront in pursuing issues of biotechnology development and applications.

Kenya also continues to address the concern of ensuring that safety issues are adequately addressed. Hence, in this workshop, the coordination and implementation of the biosafety guidelines has been recognized as being very crucial in all future activities of biotechnology. Towards this, the National Council for Science and Technology has established a *Biosafety Clearing House*, which will enable this country to fulfil the obligations of all the protocols related to these issues especially in connection to the Advanced Informed Consent and the timely decision-making required by all the biotechnology stakeholders.

Prof. King'oriah also reported that there been renewed effort at global, regional and national levels to initiate activities that would enable countries to prepare national biosafety and biosecurity guidelines, and to even harmonize regional guidelines and regulations so as to be able to use and apply biotechnology judiciously within the human ecosphere. Moreover, international technical guidelines have been produced by UNEP. These are important because they not only compliment the existing individual national biosafety guidelines but are also useful to those countries that have no existing guidelines.

The NCST Executive Secretary introduced international biosafety experts present in the workshop, namely Dr. Fee Chon Chong-Low UNEP-GEF Task Manager from Geneva, Dr. Sivramiah Shantharam, Assistant Professor of Genetics at Iowa State University, Dr. Seetharam Annadana, Consulting Biotechnologist ASR BIOTEC, Wageningen University, Plant Research International and Dr. Charles Gbedemah UNEP-GEF Regional Coordinator, Nairobi.

He introduced local experts who included Prof. Titus Mukiama, Mrs. Rachel Shibalira, Mr. Harrison Macharia, Dr. Phelix Majiwa, Dr. Francis Nang'ayo, Dr. Benjamin Odhiambo and Dr. S. Gichuki.

After giving the objective of the workshop, which was to deliberate on handling GMOs requests (applications) for authorizations for certain activities, such as contained trials, confined trials, field test releases of GMOs in the environment and commercialization of GMO products in line with international obligations such as Cartagena Protocol for the development of GMO and LMO products, Prof. King'oriah then invited Hon. Dr. Kilemi Mwiria to address the distinguished guests and officially open the workshop.

1.1.2 OPENING STATEMENT BY HON. DR. KILEMI MWIRIA, ASSISTANT MINISTER FOR EDUCATION, SCIENCE AND TECHNOLOGY

Hon. Dr. Kilemi Mwiria in his statement (see Annex 4 for full text) expressed appreciation for joining the workshop participants once more after the workshop in White Sands Hotel, Mombasa in November last year. He thanked the UNEP-GEF and in particular Dr. Fee Chon Chong-Low and Dr. Charles Gbedemah, the project personnel and the members of the National Coordinating Committee for tirelessly designing the activities of the UNEP – GEF programme according to the Cartagena Protocol, an endeavour that will lead Kenya towards the safe application of the use of GMOs.

He reminded the participants that in 1998, the NCST produced the regulations and guidelines for safety in biotechnology which provided a base for the establishment of the NBC and IBCs as well as identifying the competent authority as the NCST. In 1999, under the framework of the UNEP/GEF Biosafety Enabling Activity, a National Biosafety Framework was produced based on an assessment of the status of biotechnology and biosafety in the country. On 15th May 2000, Kenya signed the Cartagena Protocol on Biosafety and ratified the protocol on February 2002. The protocol is in force since September 2003 after ratification by 50 countries. To date more than 100 countries have ratified the protocol.

Hon. Dr. Mwiria said that the main goal of this programme that Kenya started in September 2002 is to support the implementation of the objective of the Cartagena Protocol, which has enabled the country to establish an effective biosafety management system. This system will be strengthened by capacity building and national infrastructure for LMOs import/export, handling, transport and release in the country. The National Biosafety Framework will be effectively established through the approval of the Biosafety Act, and the implementation of the national regulations and guidelines for safety in biotechnology.

He told participants that the UNEP-GEF project on the implementation of the National Biosafety Framework for Kenya started in September 2002 and will end in September 2005. Through the

programme, the Kenyan Government has developed a biotechnology policy, which has been forwarded and is awaiting cabinet approval.

Under the regulatory, a Biosafety Bill has been developed and the draft bill has been approved at the AG's Chamber. This Bill when enacted shall apply to the contained use, introduction into the environment, import and export of GMO's that may have an adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health. The Bill also requires the competent authority to promote awareness and education of the public. The competent authority shall also publish notices concerning proposals and decisions on applications.

To date, the Regulations for GMO trials under the Science and Technology Act developed and first issued in 1998, have been applied in GM trial approvals of sweet potato, rinderpest vaccine, Bt. Cotton, Bt. Maize and transgenic cassava.

Hon. Dr. Mwiria emphasised on the need to give biological security adequate attention because of its critical importance and noted that inviting scientists to this forum to learn the safety of biotechnology and biosafety issues was a fortunate occurrence. He then welcomed participants to a healthy deliberation and declared the training workshop officially opened.

1.1.3 Responses to the Opening Statements

The following salient points emerged from the opening session:

- Since 1990 Kenya has made significant strides in participating the development of biotechnology by way of developing a national biosafety framework, guidelines and regulations and identifying the NCST as the competent authority for all biosafety issues.
- There have been attempts to harmonize biosafety requirements at the regional level. The secretaries of Science and Technology in four (4) countries in the region work closely together.
- UNEP/GEF has collaborated in the development of Technical guidelines to ensure the safe development and use of biotechnology in Kenya.
- The aim of this workshop is to develop a system for handling requests and authorization for GMO introductions and release in Kenya.
- Kenya is in the process of human capacity building and building of infrastructure for dealing with biosafety issues.
- The National Biotechnology and biosafety Policy has been submitted to the Minister for Education Science and Technology for further forwarding for cabinet approval.
- The National biosafety bill has been developed and approved by the Attorney General.
- The country has to be prepared to take risks and carryout trials, and not just remain conservative, so that Kenya can develop means and ways to cope with the challenges like frequent famines. Methods of doing this must include enhancing investment in research and biosafety.
- In this regard advocacy, education, the development of databases and information sharing are important with a view to develop change of behaviour/ arrogance and political will.

- We need to put in place mechanisms to make sure that fears and myths are adequately addressed. We need as a country to develop strategic plans based on our needs and not just follow plans developed by donors.
- Scientists in this field should lobby using understandable language so that the government can adopt a workable policy.

1.2 Overview of this workshop

Following general introductions, Mr H.K. Macharia gave an overview of the workshop programme. He said that a policy on biotechnology and biosafety has been developed and submitted to the government. A Bill has also been developed and is awaiting the approval of the policy. When enacted, the Bill is expected to guide the regulatory regime for biosafety. A system is in place on how to handle notifications or requests for authorisations for certain activities, such as contained, confined trials, field releases and commercialisation of GMOs. The system typically provides for risk assessment and public participation. Other systems include one for monitoring and inspections and one for public information about the development and implementation of the National Biosafety Framework and these too are in the process of development.

The objectives of the workshop were to train the NBC, IBC and regulatory agencies to handle requests (applications) as stated under the Cartagena protocol. This included training in:

- Procedures and guidelines for application, reviewing of applications and inspection and monitoring of trials on GMOs as per International Norms;
- Kenyan Obligations and rights under the Cartagena Protocol with special emphasis on Risk Assessment;
- Implementation of Article. 8,9,10 and 15 of Cartagena Protocol on the proposed Biosafety Act of Kenya;
- Administrative Tasks and Institutional Requirements under the Cartagena Protocol
- The general principles and procedures for risk assessment including decision-making, in relation to Cartagena Protocol;
- Reach agreement on the way forward.

2.0 PRESENTATIONS

2.1 Biosafety Requirements and Institutional framework

2.1.1 Country Obligations and Rights under the Cartagena Protocol on Biosafety by Charles Gbedemah

Since early 1990s, Biotechnology is growing rapidly and LMOs are traded across borders. There was a sense of urgency to develop an international regulatory framework to address safe transfer, handling and use of LMOs.

In 1995, Parties to the Convention responded to this challenge by launching negotiations on a legally binding agreement that would address potential risks posed by Living Modified Organisms (LMOs). They recognized that while modern biotechnology has great potential for human being, it must be developed and used with adequate safety measures for the environment and human health.

After five year intensive negotiation, the Protocol was adopted in January 2000. The negotiation process was open to all countries and organizations, and participated by more than one hundred countries, NGOs and industry. The adoption of the Protocol was a historical moment and reflected a broad consensus on the need to take action on biosafety.

The Protocol sets out a comprehensive framework for international cooperation aimed at ensuring safety of transboundary movements of LMOs, or in other words, trading in LMOs. It strikes a balanced approach to meet the needs of consumers, industry and environment.

The main job of the Biosafety Protocol is to protect biodiversity from the potential risks posed by LMOs. It establishes a procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. Decisions are communicated to the world community via the Biosafety Clearing-House (BCH), a mechanism set up to facilitate the exchange of information on, and experience with, GMOs.

Dr. Gbedemah then talked the participants through the operation of the Protocol, and explained some of these procedures in greater detail.

Scope (Article 4)

The Protocol covers the transboundary movement, transit, handling and use of LMOs that may have adverse impacts on biodiversity and human health, except for pharmaceuticals that are covered by other international agreements or organizations.

Rights under the Protocol

The Protocol provides a number of rights to Parties. For example, a Party has the right to:

- Exercise sovereignty over its territorial sea, exclusive economic zones and their continental shelves in accordance with international law (Art. 2.3)
- Take any action that is more protective than that called for in the Protocol (Art. 2.4)
- Require additional relevant information, beyond the minimum specified under under Art. 7.1 (i.e. Annex 1) and Art. 11.1 (Annex 2) for LMO-FFPs, in accordance with its domestic regulatory framework (Art. 10.3c and Art.11.3)
- Regulate the transport (transit) of LMOs through its territory under its domestic regulatory framework consistent with the Protocol (Art. 6.1)
- Review and change an earlier decision (either negative or positive) regarding an intentional transboundary movement at any time, in light of new scientific information on

potential adverse effects, and inform any notifier previously notified and the BCH, within thirty days about the new decision and the reasons (Art. 12.1)

- The Party of import may, at its discretion, require a risk assessment for subsequent imports in instances where decisions taken on initial imports have been subjected to a review (Art. 12.4)
- A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement (Art. 9.4)

A failure by the Party of import to acknowledge notification shall not imply consent (Art. 9.4).

The Protocol gives provisions for the implementation of biosafety activities as follows:

a) Prior to entry into force of the Protocol:

Designate and notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities (Art. 19.1 & 19.2)

Make available to the BCH relevant details setting out its point of contact for the purposes of receiving notifications under this Article 17 on "unintentional transboundary movement of LMOs likely to have significant adverse effects"

b) During implementation of the Protocol

General obligations

- Take necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol (Art. 2.1)

- Ensure that the development, handling, transport, use, transfer and release of any LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity (Art. 2.2)

Optional

Take into account available expertise, instruments and work of other competent international forums in risks to human health (Art. 2.5)

Main Pillars

The main pillars of the Cartagena Protocol are:

- AIA procedure
- Risk assessment
- Risk management
- Biosafety clearing house
- Safe handling, transport and identification

Advanced Informed Agreement (AIA)

The Protocol provides for differentiated procedures for LMOs for intentional introduction into the environment, and LMOs intended for direct use as food, feed or for processing. All LMOs to be intentionally introduced into the environment are subject to the AIA procedure. The exporter must provide detailed information in advance of the first shipment. The importer may then authorize or refuse the shipment, based on the risks identified in the risk assessment.

Notification

The Party of export must notify the Party of import prior to the first international transboundary movement of an LMO intended for introduction into the environment of the Party of import. Exporter must provide, as a minimum, information in Annex 1. Each Party of export must legally require its exporters to ensure that information in the notification is accurate.

Acknowledgement

Party of import must acknowledge receipt within 90 days and state whether the notification contains the minimum information required (in Article 8) and whether the importation should proceed according to national law or to the decision procedure in Article 10.

Decision Procedure

If the Party of import, in its acknowledgement of receipt of notification, opts to proceed according to decision procedure in Article 10, then the Party of import carries out a risk assessment (with costs borne by the exporter), or requires the exporter to carry it out, in accordance with Article 15 and Annex III. However, the onus is on the Party of export to establish the harmless nature of the LMO in question.

The party of import communicates, with 270 days, its decision to the Party of export, and the Biosafety Clearing-House, and the reasons why, i.e. whether: i) approval with or without conditions; ii) prohibition/ refusal; iii) request for additional information or iv) extension of decision-making period beyond the 270 days.

Exceptions to AIA

Transboundary movement of pharmaceuticals that are covered by other international agreements or organizations is not covered by the scope of the Protocol, and hence is not subject to the AIA procedure.

In addition, the AIA Procedure does not apply to LMOs in transit or destined for contained use. Once the Protocol is in force, the Meeting of the Parties will also have the power to declare certain LMOs “safe”, and exempt from the AIA procedure.

Finally, LMOs for food, for feed, or for processing, are subject to a slightly modified procedure. LMOs intended for direct use as food or feed, or for processing, are subject to a simpler procedure in which a Party informs others of its decision regarding domestic use of such

organisms via a Biosafety Clearing-House. Such decisions, which include placing on the market, must be notified to the BCH within 15 days.

Decisions regarding field trials are not included under the international notification process.

Risk assessment procedure

The risk assessment procedure is elaborated in Annex III of the Protocol, and it is aimed at identifying and evaluating the potential adverse effects of LMOs on conservation and sustainable use of biological diversity (including risks to human health).

Precautionary principle

The risk assessment procedure must be based on a scientifically sound and transparent, case-by-case assessment. The precautionary principle applies, i.e. a lack of knowledge or scientific consensus does not mean a lack of risk.

Measures to manage and control risks (Article 16)

Ensure that LMOs are observed for an appropriate period before use, taking into account life-cycle or generation time

Information Sharing

Article 20 of the Protocol established an international Biosafety Clearing-House (BCH). The role of the BCH is to facilitate exchange of scientific, technical, environmental and legal information and experience with LMOs, and to assist Parties in implementing the Protocol.

Dr. Gbedemah informed the participants that he would be providing a hands-on training session on the pilot phase of the BCH on Friday, the 28th August 2004 and would go into more detail regarding its operation then.

Handling, Transport, Packaging and Identification

Shipments of different categories of LMOs (i.e. LMO-FFPs, for contained use and for intentional introduction into the environment) will be accompanied by documentation with varying details.

Documentation for:

1. LMO-FFPs, will clearly identify them as “may contain” LMOs, not intended for introduction into the environment and contacts (details to be defined by COP-MOP);
2. Contained use: clearly identifies them as LMOs, specifies conditions for safe handling, storage/use and contact details of consignee;
3. For introduction into environment: clearly identifies them as LMOs, specifies the identity and relevant traits and/or characteristics; any requirements for the safe handling, storage, transport and use and contact and declaration that the movement is in conformity with the Protocol.

Capacity-building

Capacity-building is essential to deal effectively with the provisions of the Biosafety Protocol, as the effective implementation of the Protocol would depend on adequate internal capacities. Many countries, particularly developing countries, do not yet have the capabilities to deal with the known and potential risks associated with LMOs.

Training needs

In particular, developing countries need to ensure they receive scientific and technical training in biotechnology management; training in risk assessment and risk management; and develop appropriate technological and institutional capabilities.

Roster of experts

The COP has established a roster of experts in biosafety to assist developing country parties and countries with economies in transition. Parties to the Convention are currently submitting names for the roster to the Secretariat.

Provisions to be Elaborated

Article 27 of the Biosafety Protocol requires the first meeting of COP-MOP to:
"Adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms". Currently gathering information on national, regional and international agreements to prepare the inter-governmental process.

Under Article 34, COP-MOP will consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of the Protocol, and to address cases on non-compliance. Importantly, the main objective of the compliance regime is to assist Parties in complying with their obligations under the Protocol.

The Protocol Architecture

<table>
<tr><td colspan="4">Objective</td></tr>
<tr><td colspan="4">Precautionary Approach</td></tr>
<tr><td>▪ AIA Procedure
▪ Procedure for FFP</td><td>▪ Risk Assessment
▪ Risk Management</td><td>▪ Handling transport packaging Identification
▪ documentation for shipment</td><td>Info Sharing</td></tr>
<tr><td colspan="4">SUPPORTING MECHANISMS</td></tr>
<tr><td colspan="4">BCH, Capacity Building, Compliance, Liability</td></tr>
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2.1.2 Implementation of Article 18 of Cartagena Protocol on Biosafety with respect to the Biosafety Act of Kenya by Ms Rachel Shibalira

She informed participants that Kenya's National Biosafety Framework is composed of elements that include:

- Policy - since Kenya requires it to precede law;
- Regulatory regime;
- Strategy;
- System to handle notifications/requests for permits;
- Systems for follow-up: Enforcement and monitoring for effects on the environment;
- Public participation: Part of procedural rights in environmental decision-making.

The draft Biotechnology and Biosafety Policy is awaiting presentation to the Cabinet for approval and further forwarding to Parliament. The policy's main objective is to provide a framework for the safe development and application of biotechnology.

Biosafety Regulations exist and have been operative since 1998 predating the Cartagena Protocol. However, due to the reality that these regulations lack the legal machinery to back them, and also that existing legislation is limited since it is submerged in sectoral mandate and does not align sectoral laws with the broader national goals, a Biosafety Bill has now been drafted. The draft Bill is at the Attorney General's Chambers awaiting adoption of the policy by Parliament. It is described as an Act of Parliament to regulate biotechnology and biosafety matters. Its objectives are to ensure an adequate level of protection in the safe transfer, handling and use of GMOs that may have an adverse effect on the environment and also, to establish a transparent and predictable process to review and make decisions on such GMOs and related activities. The Bill establishes a National Biosafety Authority, contains provisions on handling requests for approvals (contained use, confined use, introduction into the environment, importation and placing on the market, export, GMOs in transit etc.), handling of confidential information, reviews and appeals, licensing, liability and redress etc.

The proposed legislation is backed by a broad policy and strategy to link all existing legislation while providing a pivotal basis for biotechnology development and biosafety regulation, in line with the Cartagena Protocol which Kenya ratified in May 2000. The locus is still the Ministry of Education, Science and Technology but there is need to synchronize this with the Environmental Management and Coordination Act which established NEMA as a regulatory institution in environmental matters and has biotechnology as an activity requiring regulation as part of EIA.

The draft Biosafety Bill adopts Article 8 of the Protocol which deals with notification and application procedures. Article 9 deals with acknowledgement of receipt of notification which in the Kenya context shall be within 15 days of receipt of notification as opposed to 90 days in the Protocol. Article 10 deals with the decision procedure which in the Kenya context shall be 150 days as opposed to 270 days in the Protocol.

Article 15 deals with Risk Assessment. In the Kenyan context this shall be a risk audit based on the application dossiers. All the 5 steps for Risk Assessment indicated in the Protocol have been adopted by the proposed Kenyan legislation. The legislation also adopts Article 18 of the Protocol which deals with the handling, transport, packaging and identification of LMOs that are subject to intentional transboundary movement.

2.1.3 Administrative Tasks and Institutional Requirements under the Cartagena Protocol by Dr. Fee Chon Chong-Low

Dr. Fee Chon Chong-Low elucidated the administrative and institutional requirements for smooth implementation of the Cartagena Protocol on Biosafety (CBD) as follows:

Requirements under CPB:

- AIA procedure (Art. 7)
- Notification for export (Art. 8)
- Acknowledgement of receipt (Art. 9)
- Decision procedure (Art. 10)
- Risk Assessment (Art. 15)
- Risk Management (Art. 16)
- CNA and NFPs (Art. 19)
- BCH (Art. 20)

How should we handle applications? What do we need?

Imagine that you are an applicant and ask yourself the following questions:

- Where and to whom to apply?
- Where is the needed information?
- Are there forms to be completed?
- How many sets are needed?
- Is there a fee?
- What kind of payment?
- How many sets of documents are needed?
- In what language?

Administrative Tasks

- Before application it is important to:
    - Appoint National Focal Point (NFP)
    - Prepare information on National Biosafety Framework *e.g.* guidebook, leaflet, etc.
    - Make information available to public (website, guidebook)
    - Train support staff (technical, enforcement, administrative)
    - Develop “checklist” for information needed for risk assessment, risk management and monitoring
    - Draft regulations and statutory forms (notification, application, revocation, cessation order, etc.)

    - Set Standard Operating Procedures (Confidential Business Information - CBI, requests, appeal, etc.)
    - Determine timeframes, and fees
- Receiving an application
    - Receive application
    - Check if application is needed
    - Ascertain process procedure (notification, application)
    - Start file, provide a file number
    - Issue receipt (if fee required)
    - Ensure mandatory information provided
    - Check correct copies of application received
    - Acknowledge application (within a set time frame)
- Preparation for review
    - Check adequacy of data (maps, tables, gene sequence, etc.)
    - Request for more information/data from applicant (if necessary)
    - Identify and validate CBI
    - Separate CBI from application
    - Disseminate information document to:
        - Scientific Advisory Committee (SAC).
        - Relevant Ministries & Agencies
    - Inform public
- The review process
    - Convene meeting of Scientific Advisory Committee (SAC)
    - Receive recommendation from SAC
    - Receive and collate comments from relevant Ministries, public
    - Forward advice to decision making body (NBC/NEA/NCC)
- Decision making
    - Convene meeting of NBC
    - Receive decision from NBC
    - Prepare decision document
- Communicating the decision
    - Communicate decision to applicant in writing (270 days)
    - Close file
    - Deposit decision in web page and BCH
- Other matters (Monitoring, Appeal, Review, etc.)
    - Identify and inform inspectors to monitor and receive reports
    - Receive new information
    - Receive appeal (against decision)
    - Issue revocation order
    - Receive public comment

2.1.4 The General Principles and Procedures for Risk Assessment, in relation to Cartagena Protocol by Dr. S. Shantaram.

Dr. Shantaram's presentation focused on the main areas as underscored here below:

Principles and Procedures of Risk Assessment

- Case by case basis
- Relative and comparative risk assessment
- Principle of familiarity
- Precautionary principle *vs* precautionary approach
- Known to unknown
- Flexible not rigid – COST!!! ensure that it does not become unreasonably too expensive
- Science based
- Scientific consensus
- Evidence based
- Environmental Assessment (EA)
- Environmental (Ecological) Impact Assessment (EIA)
- Confined *vs* Contained
- Small Scale, large scale and commercial
- Regulated *vs* unregulated *vs* deregulated

Review of Environmental Release

- Scientific and technical data requirements
- Complete identification of the GMO
- Unique identifier of the transformed event
- Morphological, physiological, biochemical and molecular characterization of GMO
- Genetic stability of the GMO – site of gene insertion, copy number, Mendelian inheritance analysis

Environmental Assessment

Environmental Assessment comprises of monitoring, data collection, mitigation and reporting. It should center on the possibility for gene flow, weediness, pest or pathogen effects, toxicity and also the effects on target and non-target organisms (biodiversity). Other areas of focus should be the impact on agriculture, the impact on biodiversity, the human and animal safety and on food and feed safety (allergenicity and toxicity).

When carrying out environmental assessment, the:

- Physical boundary of the environment must be defined.
- Test site must be described.
- Physical parameters must be defined.
- Phyto-geography of the test site surroundings must be known.
- Current cultivation practices must be described.

Ecological Assessment

- Identifies adverse ecological effects over a long term.
- Realistic within temporal and spatial limits.
- Designed to gather data that will have predictive value.
- Help reduce uncertainty.
- All inclusive and comprehensive.
- Must be systematic.
- Must be iterative.
- Science based.
- Must use Good Development Practice (GMP) methodology.
- Should have a clearly identified end point.
- Help manage risks following risk characterization.
- Must use tiered approach: where Tier 1 uses evaluations based on available data, Tier 2 makes use of collected data and Tier 3 uses information on the modified plant that could alter ecology in a way distinct from the unmodified organism.
- Must be able to predict long term impacts.
- Must be able to identify mitigation procedures.
- Must assist in future technology development that would have the least impact on the environment.

2.1.5 Discussions

The following issues arising from this session were discussed.

Cartagena Protocol was ratified on 29th January, 2000. The aim was to give a balanced approach towards biotechnology development and use. The objective is to ensure the safe development, transfer and use of GMOs.

The Protocol gives a country leeway to develop its own procedures and systems for regulating the development and use of biotechnology. In the Kenyan proposal, acknowledgement of receipt of notification as per Article 9 should be within 15 days of receipt of notification as opposed to 90 days in the protocol, while the decision procedure as per Article 10 will be 150 days as opposed to 270 days in the Protocol. All the 5 steps for Risk Assessment indicated in Article 15 of the Protocol have been adopted by Kenya.

The participants were advised that there is need to re-look at the timelines of acknowledging receipt of application (15 days) and review of applications (150 days) especially in view of the various administrative tasks and institutional requirements that were brought to light during this session. Participants were advised that Kenya should use the ceiling timelines recommended by the Cartagena Protocol. The team at the NBC must be competent to check applications for completeness.

Scientists need to be acknowledged by national authorities and their names entered into a statutory national roster of experts.

2.2 Global Applications of Biotechnology and Biosafety

2.2.1 Safe use of biotechnology for improving of human welfare in developing countries by Dr. Phelix Majiwa

Dr. Majiwa's presentation was mainly pictorial. It focused on the benefits that could accrue from the safe use of biotechnology especially in developing countries. He said that, unlike developed countries who have had to develop various techniques that employ genetic engineering, developing countries have choices when it comes to using the best tools available in addressing the challenges that exist in developing countries such as the increasing population, the frequent and unpredictable food shortages brought about by drought, diseases, pests etc., the declining nutritional levels of our foodstuffs and the unavailability of cheap medication.

He talked the participants through many examples that showed how genomics has been used in the developed world to underpin agriculture and human medicine to improve productivity and human welfare in their countries.

Investments have been made in the areas of determining the nucleotide sequence of organisms, profiling of national DNA database e.g. in Nordic countries, developing appropriate diagnostics for human and animals and protecting plants against pests. Genomics has been used to increase food quantity by enhancing multiplication of plants and animals with admirable traits. Examples of such traits include plants with insect tolerance, herbicide tolerance and plants with improved tolerance to drought, heat, acidity and salinity. It has also been used to produce more effective drugs and vaccines.

Technologies are now available that use biotechnology to increase the quality of food by producing plants that have higher nutrient content (bio-fortified plants) and by removing existing allergens and toxicants. Technologies also exist that promote environmental and biodiversity conservation through reduction in the use of chemicals, through bioremediation and through provision of accurate and fast tools for biodiversity studies e.g. characterisation through genotyping.

Developing countries should adopt those technologies that would contribute positively in solving the many challenges by increasing food yields, reducing expenditure on inputs and eventually helping to generate income.

All over the world most discoveries have come from private sector investments in biotechnology since most governments do not invest adequately and hence the need to encourage public – private sector partnerships.

2.2.2 Generating transgenic crops and basic molecular analysis of GMO Crops – Dr. S. Annadana.

The presentation was a review of the basic scientific concepts and principles employed in plant transformation using molecular biology and the various methods of molecular analysis. Transformation offers novel means to manipulate plants to withstand biotic and abiotic stress, to produce pharmaceuticals, nutraceuticals and novel products. Transgenic crops are presently cultivated on over 52 million hectares worldwide. The presentation gave specific emphasis to the key areas of DNA/gene structure, gene function, plant transformation techniques,

expression of transgenes, selection of transgenes and genetic modification detection methodologies.

The following points arose from his presentation:

- Cell differentiation is a function of regulated gene expression and does not involve loss of genetic material.
- Some genes are strictly regulated by a developmental programme and are active only in certain tissues or organs.
- Some genes are environmentally regulated, becoming active only after responding to certain environmental cues.
- The organization of DNA elements within the gene promoter and in enhancer regions is complex.
- Transcription factors interact with promoter elements to facilitate transcription.

Genetic transformation of plants is done by inserting DNA into a single cell, which is then regrown into a complete organism, the plant. Various plant genetic transformation techniques were discussed ranging from well proven techniques to highly experimental methodologies. Some of the gene delivery methods discussed were: *Agrobacterium*-mediated transformation, biolistic delivery of DNA, electropolation and PEG (polyethylene glycol)-mediated uptake of DNA by protoplasts. In all these four methods, transformation involves tissue culture wherein single transformed cells are induced to proliferate and differentiate into complete plants.

In order for the gene to be expressed as a protein, other elements must also be included in the GM construct: the promoter (or start signal), gene (coding for the new property), and terminator (or stop signal). Often, a marker gene is also included to allow for selection of transformed cells from non-transformed cells during the transformation process. It was explained that stable genetic transformation usually requires the integration of cloned DNA into the nuclear genome of the host.

The detection of genetically modified plants can have several targets: newly synthesised compounds such as fatty acids, a newly expressed protein, or nucleic acids. Various methodologies for detection of GM products were discussed, whether for DNA detection (e.g. PCR) or for protein detection, including chemical analytic methods and immunological analytic methods (e.g. ELISA or western blot).

PCR amplification of the marker gene or transgene is often taken as an indication of transgenic status of regenerants. However, Southern analysis is essential to prove the integration of the foreign gene into host genome. Also, Southern hybridization is useful to assess the number of independent insertions of transgene. Since single, unaltered transgene insertions are ideal for analysis, it is also necessary to check the presence of multicopy tandem insertions and other rearrangements at the given locus.

RT-PCR, northern and western hybridization techniques are employed to assess the expression of the introduced gene. Bioassays, if available, can also provide the functionality of the transgene product. However, in primary transgenics, somaclonal and transgene effects are confounded and hence progeny analysis is recommended.

Methods of genetic analysis were also presented. i.e. how to handle primary transgenics to obtain generations. In this context, the breeding behaviour of the plant species is the deciding factor since it has profound effect on progeny performance. Furthermore, comparisons between parent and progeny performance should take into account the consequences of breeding. Various components of phenotypic variance in selected populations were presented.

2.2.3 Discussions

The following salient points arose from discussions that resulted from the above presentations.

The use of terminator technology has been suspended. Scientists have agreed not to use the technology for at least a decade.

Genetic stability comes with selection. The principles of mendelian inheritance can be used to generate stability data but for those crops which do not propagate through seed. Kenya should determine a way of generating stability data in such cases.

Q. What motive is there behind hastening, introduction of GM products? Is it likely that in future countries, farmers would be under litigation due to presence of “my genes” in your crops which may have arisen through out crossing.

A. Already a court case (legal precedence in the US) has decided that there is no legal basis for conviction.

2.3 Review of applications

2.3.1 International Norms by Dr. S. Shantaram

The key points that emanated from the presentation are summarized as follows**:**

- Risk assessment should be key when evaluating applications for GMO trials.
- Risk assessment norms all over the world use the same scientific standards but no effort has been made towards harmonizing the norms.
- The final decision must be based on national policies, international treaties & agreements, rules and regulations and on public perception and opinion.
- A decision document and what it should contain were described.
- There is need to document decision making using the available risk assessment documents for US, EU, China etc.
- There is need for regulation to distinguish between “nice to know” and “need to know” information. This is the golden rule for risk assessment.

Criteria for Sound Decision Making

- Credibility – how and by whom the assessment was conducted; its adequacy
- Accountability – who makes the final decision and on what basis
- Transparency – both the process and the decision are public information
- Understandable - simple and easy to read and without scientific and technical jargon

What is a Decision Document?

- Record of the decision
- Information resource
- [may be] Legally binding document
- Public input or participation is critical!!!

Contents of a Decision Document

- Summary of the request namely, the nature of the request, the applicant's information and a description of the organism and activity(s).
- Rationale for developing the GMO e.g. the existing constraint and alternative approaches available.
- Safety assessment. This includes the identified risks, the consequences and implications, the proposed management measures and the appropriateness and adequacy of management measures.
- Safety concerns raised: Including a brief description, the nature of consequences and the likelihood.
- Measures to address safety concerns: Including their appropriateness and adequacy.
- Conditions, if applicable
  - Requirements for monitoring / inspection / reporting
  - Criteria for completion
  - Person responsible for implementation
- Decision
  - Approved / Not Approved / Approved with Conditions
  - Basis for decision
  - Time/date when effective
  - Grounds for withdrawal or revocation

2.3.2 Overview of previously approved applications and Kenyan procedures and guidelines

2.3.2.1 Bt. Cotton Application by Ms. Lucy Gitonga

Aims and objectives of the proposal

- Application was for the trial release of transgenic cotton expressing a protein of *Bacillus thuringiensis* subsp. kurstaki which is active in controlling a number of Lepidopteran insects.
- To establish the efficacy of the Cry IA(c) protein on these insects under field conditions
- Resistance of the cotton to the bollworm complex was expected.

Background

Cotton was introduced as one of the cash crops grown by small-scale farmers in Kenya in low rainfall and most of the semi-arid areas the latter of which cover about 87% of the landmass and is home to about 27% of Kenya's population majority of whom are resource poor.

It has a great potential in the creation of employment, both at the household and industrial level. However, its production has been on the decline for over a decade dropping from 70,000 bales (1985/1986) to less than 20,000 to date compared to a national demand of 120,000 bales annually.

The factors leading to the decline were given as:

- Inability of farmers to access finance and credit facilities
- The collapse of the Bura and Hola Irrigation schemes which accounted for roughly 20% of total production.
- Poor agronomic practices leading to low yields and poor lint quality
- Lack of reliable market and delayed payments for the delivered yields hence planting of poor quality seed
- Liberalization of the Kenyan economy which rendered irrelevant both the cotton Act No. 3 (CAP 335) and the body regulating the industry.
- Pest problems in cotton. Pests include *Helocoverpa armigera* which is capable of causing up to 100% yield loss if unchecked, cotton stainers (*Dysdercus* spp.), cotton aphids (*Aphis gossypii*) and cotton red spider mites (*Tetranychus telarius*).

Synthetic pyrethroids are the currently used pesticides but they lead to serious explosion of aphid and mite populations later in the season due to the indiscriminate effect on their natural enemies. An Integrated Pest Management (IPM) approach including chemical, cultural, biological and resistant cultivars would be the most sensible approach to the management of cotton pests.

Why Bt Cotton?

- Pest control and related activities take up about 32% of the total expenditure on cotton crop production.
- Reduced spraying with synthetic pesticides would reduce environmental pollution and deleterious effects on non-target organisms and human beings
- Reduction of foliar sprays would indirectly lead to increased activity of natural enemies.
- Reduced spraying would also reduce chances of development of resistance and cross resistance to pesticides

Requirements for application approval

- February 2001: Application made to NBC through IBC. Dossier given to experts for review.
- May 2001: First NBC meeting. Issues raised to be addressed by applicant.

- September 2001: Applicant invited to verbally present to NBC. Approved with conditions.
- November 2001. NBC reverses approval, demands that lab. and screen house impact studies on non-target insects be carried out before field trials & not concurrently as earlier ruled.
- April 2002: Applicant tables information given to IBC earlier & generated in South Africa laboratory studies on impact of Bt protein to key natural enemies and beneficial insects. (Same insects found in Kenya)
- December 2002: NBC allows importation & testing.
- February 2003: NCST issues approval letter allowing importation and testing Bt cotton in KARI-contained facilities.
- March 2004: KEPHIS issues Importation Permit to KARI for GM Bollgard Nucotn B35 and DP 5690 seeds.
- May 2004: Importation takes place.

Lessons from Bt cotton application

- The NBC took too long from 2001- 2004 to evaluate and approve importation of Bt cotton into the country.
- Lack of standard specifications for facility construction.
- There appeared to be lack of adequate understanding of the application on the side of the NBC.
- Studies (some) could be carried out concurrently to shorten testing period without compromising biosafety requirements
- Incomplete membership attendance of meetings by NBC members complicated deliberations by one meeting overturning decision of another just because different members attended
- Inconsistency in decision making at IBC level and support of the same in the NBC by some members of both committees.
- Need for incorporation of expertise in the basic fields being addressed by the GMO during evaluation and approval meetings-entomology, pathology etc.

2.3.2.2 TRANSGENIC CASSAVA APPLICATION BY DR. S. GICHUKI

Objective of application to introduce transgenic cassava line resistant to Cassava Mosaic Virus

To determine the efficacy of the transgenes in imparting resistance to casava mosaic disease (CMD) caused by ACMV and the EACMV

- AC1 Replicase gene
- DI Defective interfering particle

Background

Africa losses 25 million tons of cassava or $6-25 billion per year due to Cassava Mosaic disease. It is caused by geminiviruses and transmitted by whiteflies. Dual infection of this disease is very serious. It can be combated through breeding, complemented by biotechnology.

Biotechnology can be used to apply a pathogen derived (replicase) strategy to impart resistance to cassava geminiviruses. Using this technology, cassava plants highly resistant to CMD have been generated from a highly susceptible cultivar by integration of a single transgene

Proposed Field Trial Application to IBC

- KARI in the technical lead, in collaboration with the Danforth Center
- One-fifth of a hectare plot at Alupe
- Test transgenic plants compared to control plants, exposed to natural whitefly vector

IBC approved the application but recommended that the evaluation be first carried out in a screenhouse (contained).

Summary of NBC decision

- There was no evidence of serious environmental or food safety concerns.
- No possibilities for pollen since no flowering and also no gene flow since the trial would be in a Biosafety Level 2 greenhouse. The trial would be monitored and buds removed. Also, a reproductive isolation of 200 meters would be maintained where no cassava (*Manihot esculenta)* or wild relative (*M.glaziovii)* would be allowed.
- Material would be guarded/fenced so no eating.
- The trial would be conducted by experienced professionals: KARI, Danforth
- The disease was the most important disease of one of Kenya's most important food security crops.
- Collaborative, not-for-profit, freely given technology to benefit Kenyan farmers.
- NBC approved the application
- KEPHIS implemented the decision

Implementation

- 5 transgenic lines and two non transgenic controls introduced in tissue culture
- Trials planted in KARI-Kakamega
- Routine monitoring and supervisory visits held by KEPHIS officers

Implementation Problems

- Problems of acclimatising the plants (temperature, light, concrete floor, vegetativelly propagated crop vs seed)
- Problems of artificial inoculation with whiteflies

2.3.2.3 RECOMBINANT RINDERPEST VACCINE APPLICATION BY DR. ROSEMARY NGOTHO

Objective

To carry out confined on KARI-station field evaluations to determine the efficacy of and duration of immunity of a recombinant vaccinia virus vaccine against rinderpest in a herd of African Zebu

Background

Rinderpest is a disease of great economic importance. Efforts to eradicate it by the year 2010 are currently in place but these are hindered by the lack of a vaccine that will, unlike the vaccinia-rinderpest recombinant vaccine, be able to distinguish animals that are vaccinated and those that are infected with wild rinderpest virus. Biosafety evaluations of two vaccines under contained Biosafety Level 2 Laboratory conditions have already been carried out at KARI-Muguga prior to this application: a marked vaccine in 1998 and the recombinant vaccine between 1994 to 2002.

Lessons from recombinant rinderpest vaccine field trial application

- The process is long, tedious discouraging and unnecessarily expensive.
- Guidelines were inadequate.
- There were no fixed timelines.
- Criteria to guide the process were not spelt out.
- "Those who cannot remember the past are condemned to repeat it"-George Santayana
- To achieve a user friendly application process, the evaluation of the application should support rather than delay trials.

Keys to a smooth application process

- To ensure that applications are more specific and focused, separate forms should be prepared for laboratory contained trials, confined field trials and open field trials.
- There should be clear delineation of responsibility between the Institutional Biosafety Committees and the National Biosafety Committee. This would enable applicants to direct their applications appropriately and this would reduce the length of time required for processing applications

Recommendations

- Clear guidelines on details of information required to process applications should be provided to applicants to reduce the time taken in looking for additional information after the start of the evaluation process.
- A time frame for the evaluation process should be provided. It should not be an ad-hoc open-ended process. It should be structured with clear deadlines to be met by both the applicant and the evaluation committees.
- Specific guidelines detailing containment and operational procedures should be provided at the outset following approval.
    - The committees should consider documenting standard series;
        - Design and citing of trial sites
        - SOPs at trial sites
        - Requirements and regulations for safe transport and storage of GMOs
    - Knowing what is expected will guard against jeopardizing time-lines for trials.

- Costs for the evaluation should be clearly spelt out at both the Institutional and National Biosafety Committee levels. This would enable applicants to cost the biosafety application process for inclusion in project proposals.

2.3.2.4 APPLICATION TO INTRODUCE BT MAIZE IN GREEN HOUSE IN KARI BY DR. B. ODHIAMBO

Application:
To introduce maize seeds containing Bt Genes *cry1Ab* and *cry1Ba* for contained evaluation, seed increase and crossing into other maize lines under Biosafety Greenhouse containment.

This was collaboration between the Kenya Agricultural Research Institute (KARI) and the International Maize and Wheat Improvement Center (CIMMYT).

Objectives
- Evaluate the effectiveness of the *cry* gene events against target stem borers and other insects
- Produce leaf material for use in carrying out laboratory leaf bioassays against five stem borer species
- Produce and multiply seed and crosses in the green house for future experiments

Background
The stem borer pest is a big problem in Kenya causing significant reduction in grain yields as a result of loss of photosynthetic leaf area, dead hearts, lodging from damaged stems, increased ear rots and aflatoxins.

Issues of concern considered by IBC and NBC
- Seed handling during importation, transportation and storage
- Pollen control – possibility of unplanned release/loss/escape - Biosafety greenhouse level 2
- Disposal mechanisms for pollen, seeds, soil, plants.
- Gene components – allergenicity, toxicity
- Potential for outcrossing with wild relatives - no wild relatives in Kenya

2.3.2.5 KENYAN REGULATIONS AND PROCEDURES FOR CONTAINED USE BY DR. MIRIAM KINYUA

The '*Regulations and Guidelines'* in use were published by the NCST in 1998 with the aim of guiding the process of development, introduction and dissemination of biotechnology products.

To enable researchers to evaluate and develop GMOs under conditions which minimize the impact on the environment, it is important that containment facilities and other safeguards are used during the importation, release and large-scale experiments, manufacture and testing of biotechnology products. The containment facilities may be laboratory, greenhouses, screen houses or growth rooms and they should conform to the level/class of hazard that may be caused by the GMO.

Containment is achieved through a combination of management practices, physical barriers and biological methods intended to prevent GMO transfer or survival. Physical containment is achieved through facility design and equipment and includes; sealing, grazing (e.g. transparent material like glass), screening, airflow system, cages, location of a containment facility and other features to isolate transgenic plants, plant parts, and associated organisms from the surrounding environment. Biological containment methods include; reproductive, spatial and temporal isolation.

No harvested material or byproduct from a contained trial may be used as human food or livestock feed. All material obtained from confined trials must be disposed of by an approved method (e.g., dry heat, steam heat, incineration, deep burial, chemical treatment, or crushing).

Process of application for contained use of in Kenya

- The applicant fills the prescribed application form, giving all the details requested;
- IBC examines the application and the basis for requirement, discusses with the applicant and provides the necessary advice;
- IBC approves the application when satisfied;
- The completed application form is sent to NCST, under the covering letter signed by the institutional CEO;
- The NBC scrutinizes the application and verifies the completeness of the information provided. The applicant is requested to provide any additional information required.
- NBC approves the application when satisfied that;
    - The information given in the NCST application form is complete.
    - Staff & collaborators working with GMO are adequately trained, qualified and experienced.
    - Screen-house is completed as per NBC/KEPHIS specifications
    - Field confinement facility is completed as per NBC/KEPHIS/DVS specifications
    - Inspecting authorities NBC/KEPHIS/DVS etc. would be involved at all stages of trial
    - Measures put in place to ensure material and genetic confinement are adequate and effective.
    - Internationally acceptable Standard Operating Procedures and Good Practices would be enforced at the trial premises.
- After deliberations and finalization of the status (approval or otherwise) of the application, the NBC decision is then communicated to the principal institution/applicant with a copy to the appropriate regulatory institution.

Containment facilities are inspected prior to the introduction of GMO and also during the implementation of the trial to ensure that they comply with predetermined minimum conditions for good laboratory practice. Such facilities should have appropriate equipment to conduct biotechnological research and should have protective clothing, disposal facilities, cabinets etc. The personnel working in these facilities should understand and adhere to established procedures for handling the transgenic material. These procedures and practices should be appropriate for the assigned biosafety level.

Inspectors have authority to inspect contained trial sites during the trial for compliance with the terms and conditions of authorization. Inspectors also have the authority to inspect contained facilities that may be used for the storage of experimental genetically engineered organisms.

2.3.2.6 KENYA PROCEDURES AND REGULATIONS FOR CONFINED FIELD TRIALS BY MRS. GRACE THITAI

Once experiments have been satisfactorily performed under containment, they are then extended to the field under confinement. The confined field trials are necessary before first release.

A confined field trial is a small-scale experimental field trial of a genetically engineered organism carried out to collect the data necessary for a complete environmental risk assessment performed under terms and conditions that mitigate impacts on the surrounding environment.

Confined field trials are used for research of GMOs with novel traits to provide researchers or developers with an opportunity to:

- Evaluate the performance of the GMOs;
- Study the environmental safety of the GMOs;
- Address the criteria and information required for risk assessment;
- Generate data for registration of variety and also data which may help to determine the impacts of the GMO to the environment.

'*Regulations and Guidelines'* to guide the process of development, introduction and dissemination of biotechnology and its products were produced by the National Council for Science and Technology and published in 1998.

A draft 'Manual for Inspection and Monitoring of Genetically Modified Organisms in Kenya' has also been produced and is currently being reviewed.

Specialized government agencies carry out regulatory oversight on the safety standards of food, feed and health care products as well as on matters pertaining to animal and plant health and environmental safety. These include the Kenya Bureau of Standards (KEBS) which develops standards for food toxicants among other functions, the Public Health Department in the Ministry of Health which deals with the health and safety aspects of food and feeds, the Department of Veterinary Services (DVS) which handles issues of animal health, the Kenya Plant Health Inspectorate Service (KEPHIS) which deals with issues of crop production and protection and the National Environment Management Authority (NEMA) which handles issues to do with the environment.

International instruments that address biosafety are also used. These include the Convention on Biological Diversity (1992), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (1995), the WTO Agreement on Technical Barriers to Trade (1994), the International Plant Protection Convention (1997) and the Cartagena Protocol on Biosafety (2000). Others are the Joint FAO/WHO Codex Alimentarius Commission and the World Organisation for Animal Health (*Office Internationale epizooties* - OIE).

The main focus of existing regulations and procedures is risk management i.e. to ensure that appropriate mechanisms, measures and strategies to regulate, manage and control risks to human health and environment as identified in the risk assessment provisions regarding the use, handling and transboundary movement of GMOs are established and maintained. The regulations impose necessary measures to prevent adverse effects of GMOs on conservation and sustainable use of biological diversity, taking into account risks to human health.

GMO trials in Kenya have mainly focused on plants since there have been 5 approved plant-related applications and only one animal-related application. The approved applications have been as follows:

- To introduce transgenic sweet potato
- To introduce transgenic cassava resistant to Cassava Mosaic Virus
- Transgenic cotton expressing a protein of *Bacillus thuringiensis* subsp. Kurstaki
- Confined field trial of vaccinia rinderpest double recombinant vaccine
- To introduce maize seeds containing Bt Genes *cry1Ab* and *cry1Ba* for evaluation, seed increase and crossing in greenhouse containment

<u>The following requirements apply for a confined GMO field trial:</u>

- Duly filled NCST application form for confined field trial detailing information about the GMO.
- NBC authorisation to conduct the trial and issuance of authorisation permit/letter by the appropriate regulatory institution.
- Trial be located in an isolated site away from farms and human dwellings and a map is provided.
- Other provisions made to ensure material and genetic confinement e.g. trial site does not have animals/plants of same family within proximity, trial not accessible to un-authorised persons, trial remains restricted for the period of the trial and clear methods of achieving reproductive isolation.
- Field confinement facility completed with NBC/KEPHIS/DVS specifications e.g. trial securely fenced, trial site has one entrance/exit and a secure gate, trial site has a disinfecting trough at entrance.
- Have operational notifications (specific information display of DOs and DONTs), records and biosafety manuals.
- General inspection and monitoring before the trial, during the trial and the period of post-harvest land use restriction for compliance with the terms and conditions of authorization. Inspection is also carried out at the point of entry to address importation, storage and handling, transportation and planting. Inspectors have authority to enter and inspect the trials either having given prior notice or even without a notice in order to ensure compliance with the conditions specified in the permit and also to ensure that emergency plans exist in case of accidents. Contained facilities that may be used for the storage of experimental genetically modified organisms will also be inspected. Where **Monitoring** is a process of keeping track with the activities so as to determine whether they are on schedule and

whether they are meeting the target objective, and **Inspection** is a mechanism to check for compliance to regulations and permit conditions.

- Verification of compliance records. Records of all confined GMO field trials must be kept, including current season and post-harvest site monitoring, disposition of plant material, activities related to trial site compliance, and experimental data, must be maintained by the applicant and must be made available to the regulatory body on request.
- Supervision of disposal of material from the confined trial. No harvested material or by-product from a confined field trial may be used as human food or livestock feed without approval of the regulatory body. Progeny from any GMO trial cannot be retained for future use or planting in case of plants, without prior authorization by the regulatory body.
- Only qualified persons should handle GMOs;
- Use of internationally acceptable Standard Operating Procedures (SoPs) at the trial premises.
- Baseline survey of arthropods in GMO intended areas can be carried out concurrently with field trial.

2.3.2.7 NOTIFICATION/APPLICATION PROCEDURES FOR FIELD TRIALS IN KENYA BY DR. B. ODHIAMBO

- The applicant fills the prescribed NCST application form;
- IBC examines the application, discusses with the applicant and provides the necessary advice; This has taken some considerable time in a few past applications.
- IBC approves the application when satisfied and sends the *duly completed* application form to the NBC;
- The NBC scrutinizes the application and verifies the completeness of the information provided. The applicant is requested to provide any additional information required. The applicant may or may not be present during NBC deliberations. It sometimes takes very long for the NBC to convene.
- The NBC decision is then communicated to the applicant through the institutional chief executive officer with a copy to the appropriate regulatory institution.
- Both the NBC and IBC sittings are facilitated financially by the applicant(s). Both these committees rarely sit unless there is an application to discuss. This should change and one way of ensuring that this happens is to ensure that IBC and NBC get alternative sources of funding which are not dependent on the applicants.

In conclusion, the biosafety application process is a necessary and desirable process to ensure careful, objective and systematic evaluation of genetically modified organisms prior to release into the environment. A good application procedure should be efficient in terms of time and cost and also be effective for the applicant.

2.3.2.8 REVIEW OF THE KENYAN APPLICATION PROCEDURES, '*REGULATIONS AND GUIDELINES…*' AS APPLIED IN KENYA TODAY BY DR. PHELIX MAJIWA

Background

- Kenya wishes to reap maximum benefit from biotechnology and therefore the biotechnology developments are, and will continue to be, available primarily from collaborators, donors, well-wishers, private concerns, multi-nationals and national research efforts.
- Kenya ratified the Cartagena Protocol (CP) on Biosafety in January 2002 and intends to incorporate appropriate aspects into law through the development of a national policy on biotechnology … but the '*Regulations and Guidelines*…' predates the CP

Objectives of Regulations and Guidelines for Biosafety in Biotechnology for Kenya:

- To guide the process of development, introduction and dissemination of the biotechnology products;
- For the information of citizens, consumers, etc, regarding biotechnology products;
- For information of the interested parties.

Ministry of Research and Technical Training and Technology (at that time), instructed the National Council for Science and Technology (NCST) to produce a document to this effect. The first document was published in February 1998. Attempts have been made at revising the document, as provided for, in order to bring it up to date with recent developments … work in progress.

The *'Regulations and Guidelines'*:

- Describe recognized procedures and policies to ensure safe application of modern biotechnology and use of its products;
- Are meant to protect human health and the environment from possible adverse effects of modern biotechnology;
- Guide research managers, policy makers, producers and consumers to ensure safe use of modern biotechnology and its products;
- Cover research on recombinant DNA, categorized experiments, plant biosafety, quarantine procedures, containment and field experimentation, deliberate release of GMOs, importation of biotechnology products and sanctions to ensure compliance.
- Seek to minimize potential risks associated with development, importation, utilization or release of biotechnology products.
- Require and expect institutions, organizations and persons involved in biotechnology to be fully familiar with the potential risks to society and the environment
- Are meant to promote opportunities for the application and exploitation of products of biotechnology; to ensure public and environmental safety, particularly in accident prevention, containment and waste disposal; and, to determine the measures for risk assessment, management and monitoring of operations involving GMOs, recombinant DNA technology and products arising from the use of these.

Those involved in biotechnology should therefore endeavor to adhere to the *Guidelines* …[to] enable the country…safely exploit new opportunities created by biotechnology to maximize benefits; They …shall handle biosafety information in a transparent manner and shall operate within the conditions stipulated by the NBC, in the approval of their applications.

The National Biosafety Committee (NBC):

- Is responsible for the implementation of the *Guidelines*…
- Is responsible for all matters related to the development and introduction of genetically modified organisms (GMOs).
- Reviews relevant proposals/applications … and may recommend conditions under which the proposed work should be conducted
- Ensures that adequate testing of GMO or their products has been performed in the country of origin …
- Maintains a directory of experts in biotechnology and biosafety, as well as a directory of project supervisors …
- Keeps record of biotechnology and biosafety activities in the country.

Institutional Biosafety Committees (IBCs)

- Assist the respective institutions in drawing up proposals that take cognizance of the applicable biosafety measures;
- Advice their respective institutions on cases where biotechnological activities should be reported to NBC;
- Collaborate with NBC through their respective institutions, in ensuring the implementation of the safety measures stipulated in the *Guidelines*.

Legal status of the *Guidelines*

- The *Guidelines …* is not a legal document in strict sense of the word.
- The document forms a firm basis upon which to build other instruments required for dealing with biotechnology.
- Meant to 'provide for biosafety measures to regulate development, access to, transfer and use of biotechnology and its products…'

Process of application to import GMO/LMO into Kenya

- Write details of the requirement and discus with IBC;
- IBC to examine the basis for requirement, discuss with the applicant and provide the necessary advice;
- The applicant fills the prescribed application form, giving all the details requested and gets this approved by the IBC;
- The *completed* application form is sent to NCST, under the covering letter signed by the institutional CEO;
- The NBC Secretariat will acknowledge receipt of the application within 30 days indicating the date on which it was received.

The NBC Secretariat scrutinizes the application and verifies the completeness of the information provided using a checklist. Additional information is requested within 60 days from the date of receipt of application; otherwise it is assumed that the information provided is adequate. Deliberation on the application should be within 90 days from the date of the receipt and the NBC decision should be communicated within 150 days from the date of receipt of the application. The status (approval or otherwise) of the application … finalized within 210 days from the date of receipt.

Functions of the NBC Secretariat:

- Receiving all applications on GMOs
- Coordinating NBC meetings
- Informing the public on all applications on GMOs through gazettement
- Responding to queries on GMOs
- Keeping of records of activities involving GMOs in the country
- Establishing a database… of information relevant to biosafety
- Identify national requirements for manpower development and capacity building in biosafety
- Responds to all applicants for introduction, field testing, field release and commercialization of GMOs on instructions from NBC.
- Maintains a directory of experts in biotechnology and biosafety, as well as a directory of project supervisors approved by institutional biosafety committees.
- Keeps a record of biotechnology and biosafety activities in the country

Acknowledgements:

- Government of the Netherlands, through Kenya Biotechnology Platform, now Biotechnology Trust Africa (BTA), provided funds that enabled National Council for Science and Technology to produce the first version of '*Regulations and Guidelines*…'
- UNEP-GEF phase I, provided funds for the establishment NBC and, thus, enabling the implementation of the '*Regulations and Guidelines*…'
- Implementation of the National Biosafety Framework is currently supported through funds provided by UNEP-GEF phase II. Under this, the following are being developed: National biotechnology strategy, National policy on biotechnology, Biosafety bill, Biosafety regulations and Biotechnology guidelines.

2.3.2.9 DISCUSSIONS ON REVIEW OF APPLICATIONS

The following points arose from the discussions that followed the above presentations.

Recommendations were made by applicants on how to improve the evaluation process as follows:

- There's need for separate forms for contained laboratory trials, confined field trials, open field trials since each stage has peculiar requirements and therefore the form design should be different.

- There is need to hasten the process of evaluation and approval for importation of GMOs
- There is need for standard specifications criteria and guidelines to guide the applicants when making applications.
- There should a more harmonized working relationship between IBC and NBC so as to hasten application approval processes.

The NCST should spearhead the process of ensuring that all imports into Kenya as donations during famine are milled so as to overcome the challenge of rigorous risk assessment in times of emergencies and disasters.

Technical challenges (eg. Concrete floors in greenhouse etc) that arise due to the conditions set out by the NBC should be considered during future applications.

Applicants must give realistic time lines for conducting their trials to take care of unexpected events. The approval by NBC must also consider time frames that are realistic.

NBC approvals for contained or confined trials should not be for more than one event per line because they may behave different.

The draft bill should clearly spell out which event or cross has been approved by the NBC. Is it the parental line or is the approval also valid for subsequent crosses? Do the subsequent crosses require further regulation after release?

In Kenya once a GMO is approved it can be used in any subsequent crosses and the progeny of these crosses do not necessarily have to be approved.

2.3.3 Presentations focusing on Lessons Learnt

2.3.3.1 LESSONS LEARNT BY KENYA FROM HANDLING APPLICATIONS AND THE PROCEDURES FOLLOWED BY DR. B. ODHIAMBO

- The process has sometimes been long, tedious and expensive, e.g. the Bt cotton trial, due to a slow evaluation process and also due to applicants taking long to respond to requests for further information. The evaluation of the application should support rather than delay the commencement of trials.
- The time frame for the evaluation process is currently an ad-hoc open-ended process despite the existence of *Regulations and Guidelines*. It should be structured with clear deadlines to be met by both the applicant and the evaluation committees.
- The NBC and IBC has sometimes requested for information that may not be relevant for ensuring containment or confinement. NBC and IBC members need training so as to understand and differentiate 'nice to know' versus 'need to know' issues of containment and confinement. Need exists for incorporation of expertise in the basic fields being addressed by the GMO application during evaluation and approval meetings-entomology, pathology etc.

- Inconsistencies have been experienced in the decision made by the IBC with that of the NBC. In one instance, NBC even overturned its own earlier decision.
- There seemed not to be clear delineation of responsibility between the Institutional Biosafety Committees and the National Biosafety Committee. Streamlining this and ensuring that IBC and NBC play their roles as envisaged in the *Regulations and Guidelines* may reduce the length of time required for processing applications. The role of the IBC is to work with the applicant to ensure that the application is complete before it is submitted to the NBC by giving clear guidelines on details of information required to process applications.
- Delays in commencement of trials have sometimes been caused by the applicants ignorance of what the regulatory institutions expect in relation to the implementation of the trial. Regulatory institutions should ensure that specific guidelines detailing containment and operational procedures, such as standard specifications for trial facility design and citing, SOPs at trial sites and requirements and regulations for safe transport and storage of GMOs, should be available to the applicants on demand.
- Unlike the case currently, the scheduling of IBC and NBC meetings should not be pegged on application evaluations and the accompanying allowances from the applicants. These two committees should devise mechanisms that would enable them to sit and discuss other agenda. Costs for the evaluation should be clearly spelt out at both the Institutional and National Biosafety Committee levels. This would enable applicants to cost the biosafety application process for inclusion in project proposals.
- To ensure that applications are more specific and focused, separate forms should be prepared for contained trials, confined field trials and open field trials.

2.3.3.2 LESSONS LEARNT FROM EXISTING HANDLING APPLICATION PROCEDURES FOR GM CROPS IN INDIA BY DR. S. SEETHARAM ANNADANA

In ensuring the safety of Indian consumers, health and the environment, the Department of Biotechnology, Government of India developed the 'Guidelines for Research in Transgenic Plants' which have now been used by various institutions to evolve their own guidelines for transgenic crop development and evaluation. India's focus on transgenic development has been on rice; mustard; solanaceous and cucurbitaceae vegetables; and, wheat and grain legumes (chickpea and pigeonpea).

The import of GMOs is done on a single window entry of all imported GM materials through a national containment/quarantine facility for transgenic planting material at the National Bureau of Plant Genetic Resources (NBPGR, New Delhi). The main objectives of the facility are:-

- Facilitating the processing of the transgenic material from quarantine aspects.
- Development of probes/markers as required for the containment and for evaluation of the transgenic planting material.
- Training of the human resource in the area.

Presently, the existing quarantine facilities, glasshouses and molecular biology laboratories of the NBPGR and the National Research Centre on DNA Fingerprinting are being utilized for testing of the transgenic planting material. In addition, a medium-term storage module of the NBPGR – National Gene Bank has been allocated for storing the transgenic planting material. An environmentally safe containment facility meeting the necessary biosafety regulations of

Biosafety Level-3 is in place for the purpose of testing and quarantine of transgenic planting material. It has been finalized in consultation with various national and overseas experts.

In India, the Institutional Biosafety Committee (IBSC) is constituted as follows: One member from Department of Biotechnology (DBT) of the Ministry of Science and Technology, one (1) private biotechnologist, 1 medical professional and other from the institution. The institution pays a fee to IBC members per month.

The IBSC constitutes a committee comprising of a biotechnologist, breeder, entomologist, pathologist, agronomist, physiologist/biochemist to monitor the performance of transgenics from T_1 onwards.

A field trial needs to be approved by the IBSC and the RCGM as per DBT norms. The IBSC application form should reach the coordination unit, IBSC at least a month before the scheduled meeting of the IBSC.

The monitoring processes undertaken by the Monitoring and Evaluation Committee of the RCGM involves:

- Periodic analysis of reports of the IBSC on all imported GMOs (The IBSC of the NBPGR meets once in three months to monitor the activities of quarantine handling of already licensed imports cleared by the RCGM).
- Evaluation of the documentation procedure of the import license of every GMO imported and its subsequent reporting to the regulatory authority.
- Inspection of the quarantine handling of the GMOs during quarantine.
- Inspection of the post-quarantine handling of the material (seed and molecular probe sample maintenance).
- Inspection of the preparedness for any accidents/physical facility failure/unintended accidental release.
- Feed-back monitoring system of the utility handling of the GMO by the indenter.
- Inactivation of spills and ensured destruction of the GMO debris as per the perceived risks and adherence to the treatment protocol for all effluents and growth media materials in the containment.
- The RCGM seeks information before granting a clearance to the indenter for import of the material with documentary evidence regarding the known risks, benefits, expression levels of the transgene material, hazard to environment and human health in the country of origin before granting the clearance. The composition of the RCGM, therefore, involves competent scientists in the concerned areas of interest from genetic, molecular biological, ecological and environmental aspects.

Ref: http://www.nbpgr.nic.in for more detailed information.

2.3.3.3 DISCUSSIONS ON LESSONS LEARNT

The discussions that followed these presentations raised the following issues:

Kenya has had a total of 9 applications which have been processed by the biosafety system all of which have arisen from KARI and its partners.

There is need to improve on the level of preparedness of both IBC and NBC members to handle the applications.

Funds need to be sourced for NBC and IBC as to improve the efficiency and efficacy of the operations of these two committees.

Need for clear documented procedures. Efforts to produce administrative manuals and inspection and monitoring manuals is on going.

Need for review of composition of Committees. Experts can be co-opted into the committees on a needs arising basis.

Need for continuous reviews aimed at enhancing physical and human capacity

Need to develop an information database and a data tracking system which can give various information.

India only regulates the cross between a local line and a commercial line. Every other progeny line must be approved separately.

Government of India does not honour patents on genes and living organisms.

Farmers' Rights Acts permit multiplication of seed without permission to farmer and also permits exchange.

Education and public awareness is critical to prevent clandestine activities involving GMOs as in the case in India. These activities arise from the fact that farmers accept the technology but public guardians (NGOs) still paint a negative perception of biotechnology.

2.4 Presentations focusing on Risk Assessment

2.4.1 Assessment of potential risks to the environment and human health posed by GM crops including crops for biopharming – Dr. Shantharam

Principles and Procedures of Risk Assessment

- Does not determine efficacy
- Does not deal with socio-economic and ethical issues
- Risk Assessment = Hazard X Exposure over a time scale.
- Risk Assessment includes Hazard or risk identification, risk characterization (quantification and qualification), risk mitigation and risk communication.

Risk was indicated as a relative term and a socio-cultural construct whose importance varies from community to community. Risk assessment was described as a science and it must conform to the legal requirements. Risk assessment is multifactorial and multidisciplinary. It is a tool to make a decision, a means to an end. It must be scientifically sound, based on expert advice and also on guidelines of relevant international organizations.

The recommendation after risk assessment should be acceptable risk, manageable risk or unacceptable risk. Uncertain risk must be confirmed by collecting more information/data.

Distinction must be made between, risk assessment, risk analysis, biosafety vs environmental safety, environmental assessment vs ecological impact assessment, risk assessment vs cost/benefit analysis.

Factors governing decision making on GMOs were elucidated as National Policies, stakeholder input safety assessment public opinion and international agreements and treaties. The various options for risk mitigation, risk management, risk communication and decision making were elucidated.

It was stated that major GMO related companies worldwide have put in place a regulatory compliance plan to ensure that they comply with risk assessment system requirements.

2.4.2 Risk assessment of transgenic cassava and recombinant rinderpest vaccine – a "hands-on" exercise by Dr. Shantharam and Dr. Seetharam Annadana

These were two case studies and participants broke into two groups, one to assess a Bt cotton trial application and the other to assess a recombinant rinderpest vaccine trial application.

Two case studies were presented focusing on transgenic cassava and recombinant rinderpest vaccine in place of the Bt cotton and the virus resistant potato application in the programme. Two working groups deliberated on the two applications with the purpose of making a decision on whether to approve the applications, not approve or to approve with conditions. Stimulating and educative plenary discussions followed and the resource persons gave valuable learning experience for both case studies. It was explained that approval should be on condition that any new information that may have adverse effects on the environment and human health is communicated to the relevant authorities.

2.4.3 Legal assessment and comparison of Biosafety regulations in relation to Cartagena protocol on Biosafety, WTO and Africa Model Law by Gregory Jaffe

Dr. Gregory Jaffe, the Director of the Biotechnology Project, Center for Science in the Public Interest (CSPI), USA and also an environmental lawyer from US has worked for US government as litigator prosecuting environmental polluters. He has participated in drafting laws and regulations and works for the Project on Biosafety Systems (PBS), a component of the International Food Policy Research Institute (IFPRI)

<u>PBS Comparative Legal Analysis:</u>

Establishing a good biosafety regulatory system requires:

- A review of the biosafety systems being adopted
- A comparison to:
    - Other regulatory systems
    - African Model Law
    - Biosafety Protocol and other international agreements
- An analysis of key characteristics and components of the biosafety system
- A presentation of a roadmap forward
- An oral and written presentation of analysis

Characteristics of a Good Regulatory Regime

A good regulatory regime should have adequate legal authority. It should be comprehensive, certain but also flexible, consistent, equitable, fair, easily understandable, proportionate based on risk, workable and enforceable. It should also accommodate case-by-case scientific reviews.

The Cartagena Biosafety Protocol (CBP) is the worldwide driving force for biosafety regulation and it forms the model for legislation and regulations, including definitions, scope and procedures. The Advanced Informed Consent, Risk assessment and Risk management are key pillars of the CBP. It also addresses confidentiality, transparency, public participation and the proportionate treatment of GMOs.

Other issues addressed by the CBP include food safety, safety standards, socio-economic considerations, liability, redress, and other unresolved issues.

It is a comprehensive system that addresses processes from laboratory to table and environmental and food safety issues involving a full range of products, including crops, animals and plants producing pharmaceuticals.

CBP is a clear safety standard which is legally understandable, can be consistently applied, gives a standard of proof, describes the type of evidence required and gives a baseline on how to handle GMOs.

The CBP recommends proportionate risk based reviews i.e. the need to match risks and the regulatory process and the need for efficient use of resources. It allows for the regulatory system to focus on riskier applications.

The CBP emphasizes the need for transparency. In this respect it is essential to provide: information about regulatory process; information on individual applications; information on regulatory decisions; Biosafety Protocol requirements; information required to be released; and, the transparency trade offs (including time, expense and the protection of confidential information).

Monitoring and enforcement are activities that are essential post-approval. Monitoring is done to ensure compliance with permit obligations, to ensure that no environmental or public health consequences from the release into the environment occur, and to ensure no biodiversity harms occur. The goals of monitoring and enforcement are to address current violations and violator, deter future violations and to ensure permit conditions are adhered to. The mechanisms for monitoring and enforcement include inspections, reports, and collection of sample and evidence.

2.4.4 Monitoring and Inspection Manual by Dr. Joseph M. Macharia

The Manual for inspection and monitoring of GMOs has been developed from the existing principles derived from relevant regulations and guidelines at national, regional and international levels. The aim is to put in mechanisms that ensure regulation of Biosafety procedures during genetic modification and release i.e. the need to ensure monitoring and regulation of: the development, transport, release and large scale use of GMOs; of international projects pertaining to genetic modification and release; and of commercial activities and technologies.

Scope

The manual targets:

- All institutions and persons researching, importing, developing, using, releasing and marketing GMOs.
- GMOs at all stages of research, storage, transport, development, use, release and placing on the market.
- Safety issues regarding agriculture, public health, the environment and transboundary issues pertaining to release of GMOs.

Objectives of the Manual

- To harmonize and document the GMO inspection and monitoring procedures used by the regulatory agencies to make them consistent, transparent and in line with the national policy and legislation and also with regional and international requirements.
- To serve as a guide which provides defined procedures for risk assessment of GM processes and products so as to ensure safe research, development, use (including environmental application dealing with transit/transfer), commercialization and marketing. The guide will also ensure that appropriate contingency/emergency plans exist for responding to accidental breaches of containment/confinement and also that the commercial marketing of GMOs is properly authorized. An extra objective is to collect data that may help to complete the environmental impact assessment later during unconfined release.

In summary, the guide should provide harmonised basic performance standards and procedures for inspections during containment, confinement and field release of GMOs. It should also ensure that the conditions specified in the permit are followed and that GMOs are handled by qualified persons in appropriate premises.

The purpose is, therefore, risk assessment i.e. to identify and evaluate the potential adverse effects of GMO introductions on the research, community, and on the conservation and sustainable use of biological diversity in the likely potential receiving environment. The other purpose is to ensure that mechanisms for mitigation of risk are in place.

The potential adverse effects (risks) include the expression of toxic or allergenic compounds, increased persistence in the environment, increase in weediness, transfer of genetic material, instability of the genetic modification and other unintended effects.

The Inspection and Monitoring manual emphasises the need to:

- Ensure that proper records are kept and securely maintained on all activities involving GMOs.
- Ensure that the principal investigator and the NBC are properly advised on the appropriate risk management strategies depending on the level of the assessed associated risk.
- Continually review for compliance with the correct containment and confinement levels, facilities and procedures for use in genetic modification work.
- Continually assess the training and expertise of personnel.
- Ensure that emergency plans are adopted covering accidental spills and decontaminating procedures.

The regulatory oversight, safety precautions and monitoring procedures specified should be appropriate to the level of assessed risk and should be based on parameters which include:

- Characteristics of the GMOs
- Characteristics of the host
- Characteristics of the recipient organism
- Characteristics of the receiving environment
- Number or volume of organisms to be used
- Scale of the operation
- Levels of containment
- Procedure for waste management
- Procedure for accidents and unexpected events
- Safety of workers and use of Good Work Practices

Additional specific factors that should be taken into consideration when dealing with transgenic plants, transgenic animals, GMOs for biological control and GMOs for bioremediation are also elucidated in the manual.

The need for, and the mechanisms for, monitoring during pre- and post-release experimentation are expounded in the manual. The objectives are to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the use of the GMO or its use in the receiving environment is correct and also to identify the occurrence of adverse effects of the GMO on biodiversity and also on human health. Another objective is to determine whether the GMO occurs in the environment in which it was not intended.

Conclusion

- This manual focuses on potential risks posed by GMOs with special emphasis on the effects on human and animal health, as well as on the environmental consequences.

- The manual highlights caution that must be exercised in order to reduce the risks of transferring toxins from one life form to another, of creating new toxins or of transferring allergenic compounds from one species to another, and risks to the environment and biodiversity, which could lead to the development of wild relatives with increased resistance to diseases or environmental stresses, etc.
- The Manual contains **annexes** which indicate the containment measures required for activities involving genetic modification of micro-organisms in laboratories, plant growth facilities, animal units and in any other premises.
- The Manual contains standard checklists. By 'Checklists' is meant all necessary means that enable an inspector to evaluate the availability of all necessary inputs for safe completion of the GMO introduction or trial. Checklists identify basic infrastructure for successful GMO introductions and will range from training to equipment and consumables for fieldwork. The checklists contained in the manual are those for:
  - contained trial: laboratory activities
  - contained trial: animal units
  - contained trial: glass house and growth rooms
  - field trials
  - release of GMOs in Kenya

3.0 WAY FORWARD/FOLLOW UP ISSUES

Dr. Macharia took the participants through the discussion of issues that had arisen during the workshop and those that the participants thought required follow up. The following issues were identified for follow up.

1. The process of screening applications for completeness and assisting scientists to fill the forms should be done by the IBC. This process requires review so that it can become smoother and in line with the Cartagena Protocol.

2. It was agreed that the timelines given in the Cartagena Protocol should be adopted in Kenya's draft Biotechnology and Biosafety Bill e.g. timelines for acknowledging receipt of application (15 working days) and review of applications (150 working days), especially in view of the various administrative tasks and institutional requirements that were brought to light during this Workshop. The team at the NBC must be competent to check applications for completeness.

3. Which organization will be the focal point for Kenya on biosafety issues as opposed to the competent authorities/ regulatory agencies? What kind of relationships should there be between the focal point and the competent authorities.

   The National Council for Science and Technology/Biosafety Authority shall be the focal point for Kenya on biosafety issues. The competent authorities/regulatory agencies should then provide information of related activities to this focal point to CBD.

4. Is the process of tracking, filing and record-keeping adequately addressed in the regulations? Yes. However, mechanisms are being put in place to enable information on applications to introduce GMOs to be available on internet.

5. Once a GMO event or cross is approved in Kenya do subsequent crosses or progeny require further regulation? Is this clearly captured in our draft biosafety bill and/or regulations? If not, what's the best way forward? Do we adopt the Indian, EU, USDA or a new methodology?

   Participants agreed that this issue was substantial and it required a different forum to discuss whether one application was sufficient for progeny and uses or whether different approvals should be given. The approach in determining this must, however, be safe but encourage trade and be convenient to applicant.

6. There is need to define what small medium/large scale trial means in terms of size (in the up-coming regulations, law and policy).

7. It was agreed that different application forms should be developed for the various activities such as containment, confinement and releases. These forms should be relevant for plant, animal, fish and micro-organisms issues. Participants were informed that the NCC is in the process of developing separate forms for contained laboratory trials, confined field trials, open field trials since each stage has peculiar requirements and therefore the form design should be different

8. It was felt that there was a need to change regulations/legislation to cater for confined field trials as opposed to the currently existing "open quarantine" provisions. The regulations should define quarantine. Remove "quarantine" for confined trials.

9. Legislation/regulations must be clear on who should sign application forms and hence be held liable. Participants agreed that the institution should be liable. The applicant is only an agent of the institution. The Act must define applicant as institution and not the agent of the institution. This should be taken care of by the statutory law? The Chief Executive of the institution should then be responsible and hence liable. The regulations should be clear on what the responsible officer is liable for and should also apportion liability. Participants were informed that cases of liability are already taken care of in common law?

10. There is need for scientists to be acknowledged by national authorities and their names entered into a roster of experts as required by the Cartagena Protocol.

11. There is need to hasten, with proper checks, the process of evaluation and approval for development, importation of GMOs. One way to do this would be to ensure that the IBC assists the applicant when filling the forms. A suggestion was made that, like in some countries, institutions should employ a Biosafety Officer for the purpose of assisting applicants to fill applications to introduce or develop GMOs. This officer would be a member of the IBC and would also double up as an internal inspector/auditor of GMO related trials?

12. There is need for standard specifications, criteria and guidelines to guide the applicants when making applications. Existing guidelines for IBC require that IBC be more involved in guiding applicants to fulfil NBC application requirements. It was recommended that IBC members be further trained to enable them achieve this.

13. There should be a more harmonized working relationship between IBC and NBC so as to hasten application approval processes and the need for further tailor-made training of members of both committees so as to enable them to understand and play their roles effectively was emphasised.

14. There is need to harmonize thoughts and approaches between the legal office and the scientists so that upcoming regulations can reflect the science behind the process. In this regard, there is need for a tailor-made course involving the legal officer and the scientists.

15. The need to diversify sources of funding for IBC/NBC activities to allow sustainability was emphasised especially considering that the UNEP_GEF programme was coming to an end in 2005. In the mean time applicants should continue funding (a fee) for sustainability. In the long run, IBC/NBC should be able to meet using government funds even for business that does not involve evaluation of applications. For this to happen, NBC activities should be factored into the NCST budgets and allocations. Funds may also be raised through fees (AIA). Another idea that was floated was that institutions should recognize IBCs and therefore fund them.

16. The draft biosafety bill/regulations should adequately address upcoming novel technologies that are developing and will develop (e.g. Would Kenya want to use a food crop as a BioPharm plant?)

4.0 CLOSING CEREMONY

The workshop was closed by the Minister for Agriculture Hon. Kipruto Arap Kirwa in a speech read on his behalf by the Provincial Director of Agriculture, Rift Valley Province, Mr John K. Meli, after some brief closing remarks by Prof. Titus Mukiama of the University of Nairobi's Department of Botany.

4.1 CLOSING STATEMENT BY PROF. TITUS MUKIAMA OF THE UNIVERSITY OF NAIROBI'S DEPARTMENT OF BOTANY

In his closing statement (see Annex 5 for full text), Prof. Mukiama thanked the UNEP-GEF for the support they have given to Kenya during the development of the National Biosafety framework back in 1999 and in the year 2002 when the process of implementing the Biosafety Frameworks started. Through the facilitation from UNEP-GEF, members of the IBC, NBC and the NCC are now more knowledgeable and handling applications will be taking less time than before because the workshop has sorted some of the nagging problems that had been delaying the process.

He said that members of National Coordinating Committee (NCC) have formed a task force that has been requested to foresee infrastructure development to enhance the implementation of the biotechnology and biosafety programme. In this regard, the NCC has identified two centres of excellence that is the Botany department at the University of Nairobi and Kenya Agricultural Research Institute at Biotechnology centre where the infrastructure to ensure safety of bioengineered products, and their import or export, handling, transport and use in country will be put in place.

Professor Mukiama noted that the workshop had opened the minds of the members of the NBC, IBC, NCC, regulatory agencies and fellow scientists who had acquired knowledge, which will assist easier handling of application dossier and enable them carry out screening for completeness, conduct a risk assessment and finally make a decision.

He specifically recognized the emphasis given to biological security because of its critical importance and the fact that this workshop had been organised at a time when Kenya and the world at large was recognising more than ever before the potential role of biotechnology in alleviating hunger, poverty and diseases.

4.2 CLOSING REMARKS BY THE MINISTER FOR AGRICULTURE HON. KIPRUTO ARAP KIRWA, M.P – *Read on his behalf by Mr. John K. Meli, Rift Valley Provincial Director of Agriculture, Ministry of Agriculture.*

In his closing remarks (see Annex 6 for full text), Hon. Kirwa expressed his great pleasure for joining the various key stakeholders in the biotechnology industry gathered at the workshop venue.

He appreciated the fact that the evolution and growth of biotechnology including its applications are characterized by perceived and unknown risks and, therefore, the need for clear procedure and legal framework governing all aspects of biotechnology in order to guide its growth and application both in the country and its markets outside. He reminded participants that Kenya was in the forefront in the development and application of sciences including biotechnology to mitigate our limitations in the various sectors of our economy and he gave the recent opening of Biosafety Level II Laboratory by the Head of State as a case to attest to the government's commitment to develop safe biotechnological practices to improve the welfare of Kenyans. Furthermore Kenya is a signatory to the Cartagena Protocol, which requires states, or parties to establish national frameworks to ensure adequate measures in safe transfer, handling and use of LMOs that may have adverse effects on biodiversity and human health.

He gave examples of regional and international protocols and organizations to which Kenya is a collaborating party and these included African Regional Intellectual Property Organization (ARIPO), Association for Strengthening Agricultural Research in East and Central Africa (ASARECA), New Partnerships for African Development (NEPAD), Eastern African Regional Programme and Research Network for biotechnology, biosafety, and biotechnology policy development (Bio EARN), Biotechnology Trust Africa (BTA) and the Convention on Biological Diversity (CBD) among other protocols.

The Honourable Minister challenged Kenyan scientists to safely apply biotechnology to address a number of agricultural production constraints ranging from low crop and livestock yields to stress related issue of pests, diseases and drought.

He noted that in Kenya biotechnology application in agriculture has targeted the following areas:-

- Tissue culture for crop improvement through supply of disease free planting materials on crops such as bananas, citrus, sweet potatoes, Irish potatoes, ornamental flower, macadamia, pyrethrum and orchards.
- Molecular marker assisted research targeting maize breeding for pests and drought resistance.

- Transformation and degeneration of crops targeting pests and disease resistance e.g. development of Bt maize and sweet potato resistant to the mosaic virus.
- Development of rapid disease diagnostic kits.

He appreciated the role played by the African Biotechnology stakeholders Forum (ABSF) in raising public awareness on biotechnology and biosafety and ensuring broad consultation on biotechnology implementation in the region.

He emphasised on the need to mitigate perceived adverse effects of genetically modified organisms and hence the development of the Biotechnology and Biosafety Policy to manage, develop and use biotechnology in a manner that will not have adverse effects on human welfare and complement the current efforts on food production. It also strives to inform the citizens of the developments in the world of biotechnology so that they make informed choices in the use of GMOs and GM products. The relevant national, regional and international laws on biosafety will be applied on all experiments, field release and commercialization of GMOs while guarding against unethical practices in use of biotechnology.

He hoped that the required knowledge to handle requests had been imparted through this workshop to the NBC and IBC members and would be put into use when handling applications or requests of genetically modified organisms (GMOs) in Kenya.

Although the government recognized the need to enhance the use of biotechnology to address specific problems where comparative advantage existed, such activities would be undertaken in compliance with the biosafety regulations and guidelines in accordance with the proposed Biosafety Act. The government will create avenues for the public to participate in decision making process and have access to information held by the relevant authority.

He then declared the Workshop officially closed.

5.0 ANNEXES

Annex 1: List of participants

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Annex 2: Workshop Programme

Day 1 – Wednesday, 25th August, 2004

Time	**Activity**
8.30 a.m.:	Registration of Participants
9.00 a.m.:	Start of the Workshop and Introduction of Participants
9.10 a.m.:	Speech by the UNEP-GEF Project Manager Dr. Fee Chon Low Opening remarks by Prof. G. K King'oriah Opening speech by Hon. Dr. Kilemi Mwiria Ass. MOEST
9.30 - 9.45 a.m.:	Overview of the Workshop Programme- Mr. H. K Macharia

SETTING THE SCENE

9.45 - 10.00 a.m.:	Country Obligations and rights under the Cartagena Protocol with special emphasis on risk assessment – Dr. Charles Gbedemah (UNEP/GEF)
10.00 - 10.20 a.m.:	Implementation of Article. 18 of Cartagena Protocol on Biosafety with respect to the Biosafety Act of Kenya – (Rachel Shibalira)
10.20 a.m. - 10.30	Group photo
10.30 – 11.00 a.m.:	**Tea Break**
11.00 - 11.30 a. m	Safe use of biotechnology for improving of human welfare in developing countries. By Dr. Phelix Majiwa (AATF and PBS advisory member)
11.30 - 12.00p.m.:	Administrative Tasks and Institutional Requirements under the Cartagena Protocol – Dr Fee Chon Low (UNEP/GEF)
12.00 - 12.30 p.m.:	Generating transgenic crops and basic molecular analysis of GMO Crops – Dr. S. Annadana (Consultant).
12.30 - 1.00 p.m.	Discussion
1.00 – 2.00 p.m.:	**Lunch Break**
2.00 - 3.00 p.m.:	The general principles and procedures for risk assessment including decision- making, in relation to Cartagena Protocol – Dr. S. Shantaram (Consultant).
3.00 - 4.00 p.m.:	An overview of previously approved applications in Kenya (with special focus on *procedures* and specify *differences*) i) Bt Cotton – Mrs. Lucy Gitonga ii) Transgenic Cassava – Dr. B. Odhiambo iii) Recombinant Rinderpest Vaccine – Dr. Rosemary Ngotho.

4.00 – 4.30 p.m.: Tea Break

4.30 - 5.15 p.m.: Discussions.

Day 2 – Thursday, 26th August 2004

Time	**Activity**
9.00 - 9.15 a.m.:	Review of day one Proceedings –Dr. Joseph Macharia
9.15 - 9.45 a.m.:	Reviewing application as per International Norms - Dr. S. Shantaram (Consultant).
9.45 – 10.00 a.m.:	**Tea Break**

LESSONS LEARNT, KENYAN REGULATIONS AND PROCEDURES

10.00 - 10.30 p.m.:	Lessons learnt by Kenya from handling applications and the procedures followed - Dr. B. Odhiambo KARI Biotechnology Centre
10.30 - 11.00	Kenyan Regulations and Procedures for Contained Use Dr. Miriam Kinyua
11.00 - 11.30 p.m.:	Application for Introduction of Bt. Maize in the Biosafety level 2 green house complex in KARI - Dr. S. Gichuki KARI Biotechnology Centre
11.30 - 12.00 p.m.:	Discussions
12.00 - 12.30 p.m.	**Lessons Learnt** from Existing Handling Application Procedures for GM Crops in India - Dr. S. Seetharam Annadana (Consultant).
12.30 - 1.00 p.m.:	Discussions
1.00 – 2.00 p.m.:	**Lunch Break**
2.00 - 2.30 p.m.:	Kenya Procedures and regulations for Field Trials - Mrs. Grace Thitai
2.30 - 3.00 p.m.:	Notification/Application procedures for field trials in Kenya - Dr. B. Odhiambo
3.00 - 3.30 p.m.:	Confined field-trials applications, monitoring and inspection design. By Dr. Francis Nang'ayo KEPHIS
3.30 - 4.00 p.m.:	Discussions
4.00 – 4.15 p.m.:	**Tea Break**
4.15 - 4.45 p.m.:	Review of the Kenyan Application Procedures-Dr. Phelix Majiwa (AATF)
4.45 - 5.00 p.m.:	Discussions.

6.00 - 7.00p.m. NCC meeting

Day 3 – Friday 27th August, 2004

Time	**Activity**
9.00 - 9.30 a.m.:	Review of day two proceedings by Dr. Ann Wangai
9.30 - 10.30 a.m.:	Assessment of potential risks to the environment and human health posed by GM crops including crops for biopharming – Dr. Shantharam (Consultant).
10.30 - 11.00 a.m.:	Discussions
11.00 – 11.30 a.m.:	**Tea Break**
11.30 - 12.3 0 p.m.:	Risk assessment of *Bt* Cotton and virus resistant Potato – a "hands-on" exercise. - Dr. Shantharam and Dr. Seetharam Annadana (Participants break into 2 groups for separate exercise, with one consultant per group)
12.30 - 1.00 p.m.	Discussions
1.00 - 2.00 p.m.:	**Lunch Break**
2.00 - 2.30 p.m.:	Monitoring and Inspection Manual – Dr. Joseph M. Macharia
2.30 - 3.00 p.m.:	Legal assessment and comparison of Biosafety regulations in relation to Cartagena protocol on Biosafety, WTO and Africa Model Law – Gregory Jaffe (PBS Advisory Member)
3.00 - 3.30 p.m.	Discussions
3.30 - 3.45 p.m.:	Follow up Issues
3.45 - 4.00 p.m.:	Closing remarks Prof. Mukiama

Annex 3: Welcome Address by Professor G.K. King'oriah, Executive Secretary, National Council for Science and Technology.

- Hon. Assistant Minister for Education, Science and Technology Dr. Kilemi Mwiria
- Dr Fee Chon Chong-Low, UNEP-GEF Task Manager, Geneva
- Dr. Sivramiah Shantharam, Assistant Professor of Genetics at Iowa State University
- Dr Seetharam Annadana, Consulting Biotechnologist ASR BIOTEC, Wageningen University, Plant Research International.
- Dr Charles Gbedemah, UNEP-GEF Regional Coordinator, Nairobi.
- Members of the National Biosafety Committee.
- Members of the institution Biosafety committee
- Members of the National Coordinating Committee
- Distinguished scientists, scholars, ladies and gentlemen,

Sir, we are honoured to have you with us this morning to officially open this workshop on handling requests (applications) for NBC and IBC members at Merica Hotel.

Honourable Minister, the National Council for Science and Technology continues to be at the forefront in pursuing issues of biotechnology development and applications.

Honourable Minister, biotechnology is important to our society, as it is an economic empowerment tool for our farmers in agriculture. Here in Kenya we have undertaken biotechnology activities in the fields of agriculture, health, environment and trade. We have also addressed the concern of ensuring that safety issues are adequately addressed.

In this workshop the coordination and implementation of the biosafety guidelines has been recognized as being very crucial in all future activities of biotechnology. Towards this, the National Council for Science and Technology has established a *Biosafety Clearing House*, which will enable this country to fulfill the obligations of all the protocols related to these issues especially in connection to the Advanced Informed Consent and the timely decision-making required by all the biotechnology stakeholders.

Hon. Minister, Ladies and Gentlemen

There have been attempts to harmonize the biosafety regulations at regional level. The implications of release is therefore being systematically investigated before the release is authorized, and all the necessary steps are being taken to minimize potential problems – hence the need for risk assessment and risk management in the development of GMOs.

The application of safe biotechnology aimed at developing new products, which are useful in many spheres of life, has proved to be one of the best options for development, in view of rising demands caused by human population increase. The potential benefits from the use of genetically modified organisms in the areas of agriculture, human health, animal production, trade, industry and environmental management are clearly recognized. As a result, there is a

renewed effort at global, regional and national levels to initiate activities that would enable countries to prepare national biosafety and biosecurity guidelines, and to even harmonize regional guidelines and regulations so as to be able to use and apply biotechnology judiciously within the human ecosphere. Moreover, international technical guidelines have been produced by UNEP. These are important because they not only compliment the existing individual national biosafety guidelines but are also useful to those countries that have no existing guidelines.

Sir, we have international biosafety experts here with us (Dr. Fee Chon Chong-Low UNEP-GEF Task Manager from Geneva, Dr. Sivramiah Shantharam, Assistant Professor of Genetics at Iowa State University, Dr. Seetharam Annadana, Consulting Biotechnologist ASR BIOTEC, Wageningen University, Plant Research International and Dr. Charles Gbedemah UNEP-GEF Regional Coordinator, Nairobi).

Our local experts in this endevour led by Prof. Titus Mukiama (Mrs. Rachel Shibalira, Mr. Harrison Macharia, Dr. Phelix Majiwa, Dr. Francis Nang'ayo, Dr. Benjamin Odhiambo and Dr. S. Gichuki).

Honourable Minister, in this workshop the major issues that will be discussed is deliberations on handling requests for release of GMOs and decision-making. The deliberation has to be in line with international obligations such as Cartagena Protocol for the development of GMO and LMO products.

Members of National Biosafety Committee and Institutional Biosafety Committee will deliberate on handling GMOs requests (applications). The aim of the workshop will be to concentrate on a system to handle notifications or requests for authorizations for certain activities, such as contained trials, confined trials, field test releases of GMOs in the environment and commercialization of GMO products. The training workshop will be there up to Friday and I am optimistic the workshop participants will benefit a lot.

Sir, the workshop has been sponsored by the UNEP-GEF. The National Council for Science and Technology has done the organization of the workshop under the guidance of National Coordinating Committee in consultation with Dr. Fee Chon Chong-Low, the UNEP-GEF Task Manager who is here with us and she has traveled all the way from Geneva. To us sir, this is dedication and commitment.

On those few remarks, I would now kindly invite you to address the distinguished guests and the workshop participants.

Welcome, Hon. Minister Dr. Kilemi Mwiria.

Annex 4: Opening Speech for Workshop on Handling Requests (Applications) for NBC and IBC Members, 25th August 2004 at Merica Hotel by Hon. Dr. Kilemi Mwiria, Assistant Minister for Education, Science and Technology

- Prof. G.K King'oriah, Executive Secretary, National Council for Science and Technology
- Dr Fee Chon Chong-Low, UNEP-GEF Task Manager, Geneva
- Dr. Sivramiah Shantharam, Assistant Professor of Genetics at Iowa State University
- Dr Seetharam Annadana, Consulting Biotechnologist ASR BIOTEC, Wageningen University, Plant Research International.
- Dr Charles Gbedemah, UNEP-GEF Regional Coordinator, Nairobi.
- Members of the National Biosafety Committee.
- Members of the Institution Biosafety committee
- Members of the National Coordinating Committee
- Distinguished scientists, scholars, ladies and gentlemen,

May I express my gratitude for having been with you again after the workshop in White Sands Hotel, Mombasa in November last year.

May I also thank the UNEP-GEF and in particular Dr. Fee Chon Chong-Low and Dr. Charles Gbedemah who are with us today. We are honoured to be with you here in this workshop on handling request (applications) for National Biosafety Committee and Institutional Biosafety Committee members. I would like to thank the project personnel of this programme who have organised this workshop. Also thanks to members of the National Coordinating Committee who have tirelessly designed the activities of the programme according to the Cartagena Protocol. This endeavor will lead Kenya towards the safe application of the use of GMOs.

To refresh your mind a bit I would like to say that in 1998, the National Council for Science and Technology produced the regulations and guidelines for safety in biotechnology which provided a base for the establishment of the National Biosafety Committee (NBC) and Institutional Biosafety Committees as well as identifying the competent authority as the National Council for Science and Technology. In 1999, under the framework of the UNEP/GEF Biosafety Enabling Activity, a National Biosafety Framework was produced based on an assessment of the status of biotechnology and biosafety in the country. On 15th May 2000, Kenya signed the Cartagena Protocol on Biosafety and ratified the protocol on February 2002. As you are aware the protocol is in force since September 2003 after ratification by 50 countries. To date more than 100 countries have ratified the protocol.

The main goal of this programme that Kenya started in September 2002 is to support the implementation of the objective of the Cartagena Protocol. This has enabled the country to establish an effective biosafety management system which will be strengthened by capacity building and national infrastructure for LMOs import/export, handling, transport and release in the country.

The National Biosafety Framework will be effectively established through the approval of the Biosafety Act, and the implementation of the national regulations and guidelines for safety in biotechnology.

“Living Modified Organisms”, “transgenic organisms”, “recombinant DNA organisms”, have been derived through the use of techniques of modern biotechnology.

In Kenya the term “genetically modified organisms” (GMOs) is used. It is noted that the National Biosafety Frameworks typically focus on environmental safety and do not address the safety of human food and animal feed.

Although National Biosafety Frameworks vary from country to country, they often contain a number of common components:

- A policy on Biotechnology and Biosafety, which is often part of a broader national policy on biotechnology.
- A regulatory regime for Biosafety, which usually consists of a Bill or Act in combination with implementing regulations.
- A system to handle notifications or requests for authorizations for certain activities, such as contained trials, confined trials, field test releases of GMOs in the environment and commercialisation of GMOs products.
- A system for monitoring and inspections.
- A system for public information, i.e. a system to inform stakeholders about the development and implementation of the National Biosafety Framework.

The UNEP-GEF project on the implementation of the National Biosafety Framework for Kenya started in September 2002 and will end in September 2005.

Through the programme, the Kenyan Government has developed a biotechnology policy, which has been forwarded and is awaiting cabinet approval.

Under the regulatory, a Biosafety Bill has been developed and the draft bill has been approved at the AG’s Chamber.

This Bill when enacted shall apply to the contained use, introduction into the environment, import and export of GMO’s that may have an adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health.

The Bill also requires the competent authority to promote awareness and education of the public. The competent authority shall also publish notices concerning proposals and decisions on applications.

As you are aware the Regulations for GMOs trials under the Science and Technology Act were developed and first issued in 1998. These regulations enabled establishment of National

Biosafety Committee (NBC) and Institution Biosafety Committee (IBC). These regulations also provided guidelines for handling GMO applications.

To date these regulations and guidelines have been applied in GM trial approvals of
(i) Sweet potato
(ii) IRMA Project
(iii) Rinderpest vaccine
(iv) Bt. Cotton
(v) Bt. Maize
(vi) Transgenic cassava.

I understand the workshops in Merica Hotel will now concentrate on a formal training on a system to handle notifications or requests for authorisations for certain activities, such as contained trials, confined trials, field test releases of GMOs in the environment and commercialisation of GMOs products.

This whole question of biological security has been given great emphasis because of its critical importance. It is therefore fortunate that the scientists have been invited in this forum to learn the safety of biotechnology and biosafety issues.

With these few remarks, I would now kindly welcome you to a healthy deliberation, which will be presented to you on this forum by various resource persons.

With those few remarks I declare the training workshop on handling request officially opened. Thank you.

Annex 5: Closing Speech for Workshop on Handling Requests (Applications) for NBC and IBC Members, 25th August 2004 at Merica Hotel by Prof. Titus Mukiama of the University of Nairobi's Department of Botany.

- Prof.G.K King'oriah Executive Secretary National Council for Science and Technology.
- Dr Fee Chon Chong-Low, UNEP-GEF Task Manager
- Dr. Sivramiah Shantharam, Assistant Professor of genetics at Iowa state University
- Dr Seetharam Annadana, Consulting Biotechnologist ASR BIOTEC, Wageningen University, Plant Research International.
- Dr Charles Gbedemah, UNEP-GEF Regional Coordinator.
- Gregory Jaffe, director of Biotechnology project, Washington D.C
- Members of the National Biosafety Committee.
- Members of the institution Biosafety committee
- Members of the National Coordinating Committee in Biosafety
- Distinguished scientists, scholars, ladies and gentlemen,

First, I would like to thank the UNEP-GEF for the support they have given to Kenya during the development of the National Biosafety framework back in 1999 and in the year 2002 when the process of implementing the Biosafety Frameworks started. Kenya is among the four countries in Africa implementing the Biosafety Frameworks. I am very pleased to note that the facilitators from UNEP-GEF have gone another milestone to see the activities are running according to the plans proposed in the project document. We are learning and we believe that learning is a continuous process. Members of the Institution Biosafety Committee, National Biosafety Committee and the National Coordinating Committee are now more knowledgeable than when the training workshop started. The handling application will be taking less time than before because the workshop has sorted some of the nagging problems that had been delaying the process.

In Kenya the overall programme goal is to build a functional national Biosafety Regulatory System. We have already established a management system, which will support the implementation of the management and monitoring system related to the safe environmental release, commercial production and transboundary movement of living modified organisms (LMOs) in Kenya, in compliance of the obligations of the Cartagena Protocol. The National Biosafety Framework Implementation is also focusing on capacity building and the workshop we have just concluded is a good example.

Members of National Coordinating Committee (NCC) have formed a task force that has been requested to foresee infrastructure to enhance the biotechnology. In this regard, the NCC has identified two centres of excellence that is the Botany department at the University of Nairobi and Kenya Agriculture Research Institute at Biotechnology centre when the infrastructure to ensure safety of bioengineered products, and their import or export, handling, transport and use in country will be put in place.

There have been attempts to harmonize the biosafety regulations at regional level. Safety aspects of genetically engineered organisms, biopesticides and other biochemicals are being assessed on the same lines as those of synthetic chemicals, since greater risks may be involved if pathogenicity or weediness is implicated in the release of these Genetically Modified Organisms. The risk of transferring herbicide resistant transgenic crop plants needs to be critically analyzed. The implications of release is therefore being systematically investigated before the release is authorized, and all the necessary steps are being taken to minimize

potential problems - hence the need for risk assessment and risk management in the development of GMOs.

The application of safe biotechnology aimed at developing new products, which are useful in many spheres of life, has proved to be one of the best options for development, in view of rising demands caused by human population increase. The potential benefits from the use of genetically modified organisms in the areas of agriculture, human health, animal production, trade, industry and environmental management are clearly recognized. As a result, there is a renewed effort at global, regional and national levels to initiate activities that would enable countries to prepare national biosafety and insecurity guidelines, and to even harmonize regional guidelines and regulations so as to be able to use and apply biotechnology judiciously within the human ecosphere. Moreover, international technical guidelines have been produced by UNEP. These are important because they not only compliment the existing individual national biosafety guidelines but also are also be useful to those countries that have no existing guidelines.

Ladies, and gentlemen as you have realized, the workshop has opened minds of the members of the National Biosafety Committee, Institution Biosafety Committee and National Coordinating Committee.

In these workshop members of National Biosafety Committee, Institutional Biosafety Committee, regulatory agencies, and fellow scientists have acquired knowledge, which will assist easier handling of application dossier and enable them carry out screening for completeness, conduct a risk assessment and finally make a decision.

This whole question of biological security has been given great emphasis because of its critical importance. This workshop has been organised at a time when Kenya and the world at large is recognising more than ever before the potential role of biotechnology in alleviating hunger, poverty and diseases. Thank you.

Annex 6: Closing Speech by the Minister for Agriculture Hon. Kipruto Arap Kirwa, M.P at a Workshop on Handling Requests (Applications) of Genetically Modified Organisms at Merica Hotel, Nakuru, 27th August 2004 – Read on his behalf by Mr. John K. Meli, Rift Valley Provincial Director of Agriculture, Ministry of Agriculture.

Distinguished Guests, Ladies and Gentlemen, it gives me great pleasure to join you today in this special occasion which has brought together the various key stakeholders in the biotechnology industry to officiate the closing of this workshop on Handling Requests (Applications) of Genetically Modified Organisms by the National Biosafety Committee and Institutional Biosafety Committees.

Ladies and Gentlemen, as you all know, the evolution and growth of biotechnology including its applications are characterized by perceived and unknown risks. There is therefore need for clear procedure and legal framework governing all aspects of biotechnology in order to guide its growth and application both in the country and its markets outside.

I wish to state from the start that Kenya is in the forefront in the development and application of sciences including biotechnology to mitigate our limitations in the various sectors of our economy. The recent opening of Biosafety Level II Laboratory by the Head of State attests to this.

The government is keen to develop safe biotechnological practices to improve the welfare of Kenyans. It also recognizes the role it can play in poverty reduction, enhancing food security and in conservation of biodiversity, environment and industrial application.

Furthermore Kenya is a signatory to the Cartagena Protocol, which requires states, or parties to establish national frameworks to ensure adequate measures in safe transfer, handling and use of LMOs that may have adverse effects on biodiversity and human health.

Ladies and Gentlemen, the world being a global market has made it difficult for countries to operate individually in any trade. This has necessitated countries to embrace both regional and international protocols. Regionally Kenya is a member of organizations such as African Regional Intellectual Property Organization (ARIPO), Association for Strengthening Agricultural Research in East and Central Africa (ASARECA), New Partnerships for African Development (NEPAD) etc, whose activities on biotechnology will impact on us depending on our preparedness.

Internationally Kenya is party to the Convention on Biological Diversity (CBD) among other protocols which requires setting out appropriate procedures, including in particular, advance informed agreement, in the field of the safe transfer, handling and use of any LMO resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, provides the framework for development and use of biodiversity in a manner consistent with the conservation and sustainable use of the same.

It is in this respect that Kenya has formulated policies (in draft form) that attract investment and trade in relation to its regional and international obligation. The Kenyan policy on biotechnology and Biosafety while geared to satisfying the international community must safe guard the interest of Kenyans.

Ladies and Gentlemen, Kenya today faces the challenges of a poorly performing agricultural sector, which has given rise to food insecurity. Agricultural growth continues to be constrained by various factors including shortages of arable land, occasional by high population growth rate, high dependency on rain-fed agriculture, decline in soil fertility, inadequate input application, pests and diseases among others. For Kenya to remain self sufficient in food production, it is essential to have available, a new generation of high yielding varieties of crop. The use of high yielding, disease and pest resistant crops will go a long way to meet this goal. The application of biotechnology offers the promise and potential to address a number of agricultural production constraints ranging from low crop and livestock yields to stress related issue of pests, diseases and drought.

In Kenya biotechnology application in agriculture has targeted the following areas:-

- Tissue culture for crop improvement through supply of disease free planting materials on crops such as bananas, citrus, sweet potatoes, Irish potatoes, ornamental flower, macadamia, pyrethrum and orchards.
- Molecular marker assisted research targeting maize breeding for pests and drought resistance.
- Transformation and degeneration of crops targeting pests and disease resistance e.g. development of Bt maize and sweet potato resistant to the mosaic virus.
- Development of rapid disease diagnostic kits.

The region is home to several organizations that seek through regional services and networks to advance policy development, technical training, stakeholder participation and biosafety co-ordination. As regional strategies gain importance in effecting biosafety implementation, these groups could model proven mechanisms for co-operation among neighbouring countries on handling genetically modified organisms.

The African Biotechnology stakeholders Forum (ABSF) is a leading organization in raising public awareness on biotechnology and biosafety and ensuring broad consultation on biotechnology implementation in the region.

The Association for Strengthening Agricultural Research in East and Central Africa (ASARECA) has the objective to develop consensus on the specific goals, approaches and administration of regional biosafety regulatory development and intellectual property rights.

The Eastern African Regional Programme and Research Network for biotechnology, biosafety, and biotechnology policy development (BioEARN) has an objective to develop national and regional capability to assess the risk and benefits of recombinant DNA techniques.

Biotechnology Trust Africa (BTA) is engaged in the development of agricultural research priorities and providing information and training about intellectual property rights.

While it is recognized that modern biotechnology has the potential to contribute towards the improvement of human well being, particularly in enhancing food production and health care, there has been growing public concern over the potential adverse effects of the technology and its products to human health and the environment.

Potential perceived risks of genetically modified organisms in general include possibility of creating new disease microbes and allergies that may have direct negative impact on users. Other risks are the possible loss of biodiversity, environmental damage and social disparity.

In an effort to mitigate these perceived adverse effects the Biotechnology and Biosafety Policy is an attempt to manage, develop and use biotechnology in a manner that will not have adverse effects on human welfare and complement the current efforts on food production. It also strives to inform the citizens of the developments in the world of biotechnology so that they make informed choices in the use of GMOs and GM products.

Implementation of biotechnology activities will conform to national, regional and international protocols including the Cartagena Protocol on Biosafety as well as the Convention on Biological Diversity.

The relevant laws on biosafety will be applied on all experiments, field release and commercialization of GMOs while guarding against unethical practices in use of biotechnology.

The general guiding principles of the policy document in biotechnology development is based on the precautionary approach contained in principle of the Rio Declaration on Environment Development and further enhanced in the Cartagena Protocol itself which gives the parties:-

- The right to decide on importation of LMOs;
- The right to adequate information on importation of LMOs;
- The right to use the precautionary principle in decision making;
- Rights to information to adequately address the risks.

The purpose of proper handling of requests is to allow safe evaluation of genetically modified organisms.

This requires that the applicant provide adequate information required for assessment of potential risks and benefits of the requested activities.

The required knowledge to handle requests, I believe, has been imparted through this workshop to the NBC and IBC members and will be put into use when handling applications or requests of genetically modified organisms (GMOs) in Kenya.

In conclusion I wish to say that release of genetically modified organisms will be allowed after careful and comprehensive risk assessment and socio-economic issues will have been assessed.

The government recognizes the need to enhance the use of biotechnology to address specific problems where comparative advantage exists.

However, such activities will be undertaken in compliance with the biosafety regulations and guidelines in accordance with the proposed Biosafety Act.

The government will create avenues for the public to participate in decision making process and have access to information held by the relevant authority.

Finally Ladies and Gentlemen, I once more want to thank the NCST and the UNEP-GEF for organizing and funding this workshop and I now declare the workshop officially closed. THANK YOU.